

REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: GLOB1912H

Product name: **Jura Max**

Chemical active substance:

Prosulfocarb, 667 g/L

Diflufenican, 14 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Update July 2022

Applicant: Globachem NV

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Evaluation date: August 2022

MS Finalisation date: ---

Version history

When	What
November 2021	Initial submission by the applicant for approval of new product.
July 2022	Dossier update by applicant after request for additional information.
August 2022	zRMS finalized dRR evaluation

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8 Fate and behaviour in the environment (KCP 9)

Review Comments:

This document describes the acceptable use conditions required for registration of GLOB1912H, a suspension concentrate containing 667 g/L prosulfocarb and 14 g/L diflufenican for use as a herbicide in winter cereals, potato and sunflower.

This Part B document only reviews data and additional information that has not previously been considered within the EU review process.

Since this document is based on the information provided by the applicant, all review comments, additions and corrections have been made using commenting boxes or highlighted in grey.

8.1 Critical GAP and overall conclusions

Table 8.1-1: Critical use pattern of the formulated product

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
Zonal uses (field or outdoor uses, certain types of protected crops)														

1	PL, CZ, DE, BE, HU	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI), Winter durum wheat (TRZDW), Spelt (TRZSP)	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	Downward spraying	Pre-emergence (BBCH 0-09)	a) 1 b) 1	/	a) 3.2 b) 3.2	a)Prosulfocarb: 2.134 Diflufenican: 0.0448 b)Prosulfocarb: 2.134 Diflufenican: 0.0448	160-300	/	/	
2	PL, CZ, DE, BE, HU	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI), Winter durum wheat (TRZDW), Spelt (TRZSP)	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	Downward spraying	Pre-emergence (BBCH 0-09)	a) 1 b) 1	/	a) 3.0 b) 3.0	a)Prosulfocarb: 2.001 Diflufenican: 0.042 b)Prosulfocarb: 2.001 Diflufenican: 0.042	160-300	/	/	
3	PL, CZ, DE, BE, HU	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI), Winter durum wheat (TRZDW), Spelt (TRZSP)	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	Downward spraying	BBCH10-13	a) 1 b) 1	/	a) 3.2 b) 3.2	a)Prosulfocarb: 2.134 Diflufenican: 0.0448 b)Prosulfocarb: 2.134 Diflufenican: 0.0448	160-300	/	/	
4	PL, CZ, DE, BE, HU	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI), Winter durum wheat	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	Downward spraying	BBCH10-13	a) 1 b) 1	/	a) 3.0 b) 3.0	a) Prosulfocarb: 2.001 Diflufenican: 0.042 b)Prosulfocarb: 2.001 Diflufenican: 0.042	160-300	/	/	

		(TRZDW), Spelt (TRZSP)												
5	PL, CZ, DE, BE, HU	Potato (SOLTU)	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	Downward spraying	Pre- emergence (BBCH 0- 09)	a) 1 b) 1	/	a) 3.2 b) 3.2	a)Prosulfocarb: 2.134 Diflufenican: 0.0448 b)Prosulfocarb: 2.134 Diflufenican: 0.0448	160-300	/	/	
6	PL, CZ, DE, BE, HU	Potato (SOLTU)	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	Downward spraying	Pre- emergence (BBCH 0- 09)	a) 1 b) 1	/	a) 3.0 b) 3.0	a)Prosulfocarb: 2.001 Diflufenican: 0.042 b)Prosulfocarb: 2.001 Diflufenican: 0.042	160-300	/	/	
7	PL, CZ, DE, HU	Sunflower (HELAN)	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	Downward spraying	Pre- emergence (BBCH 0- 09)	a) 1 b) 1	/	a) 3.2 b) 3.2	a) Prosulfocarb: 2.134 Diflufenican: 0.0448 b)Prosulfocarb: 2.134 Diflufenican: 0.0448	160-300	/	/	
8	PL, CZ, DE, HU	Sunflower (HELAN)	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	Downward spraying	Pre- emergence (BBCH 0- 09)	a) 1 b) 1	/	a) 3.0 b) 3.0	a) Prosulfocarb: 2.001 Diflufenican: 0.042 b)Prosulfocarb: 2.001 Diflufenican: 0.042	160-300	/	/	

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for column 15 “Conclusion”

A	Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

Table 8.1-2: Assessed (critical) uses during approval of prosulfocarb concerning the Section Environmental Fate (EFSA Scientific Report (2007) 111, 1-81)

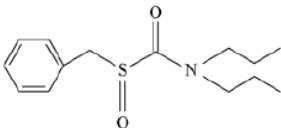
1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No.	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	Northern and Southern Europe	Winter wheat	F	Weeds	Boom sprayer	Pre- emergence up to BBCH 21	a) 1 b) 1	NR	a) 5 b) 5	c) 4.0 d) 4.0	200-400	NA	-
2	Northern and Southern Europe	Potatoes	F	Weeds	Boom sprayer	Pre- emergence up to BBCH 11	a) 1 b) 1	NR	a) 5 b) 5	c) 4.0 d) 4.0	200-400	NA	-

Table 8.1-3: Assessed (critical) uses during approval of diflufenican concerning the Section Environmental Fate (EFSA Scientific Report (2007) 122, 1-84)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No.	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	EU	Winter wheat/barley/rye	F	Annual dicot weeds, ALOMY, APESV, POAAN	Tractor mounted boom spraying	Pre- emergence; Post- emergence BBCH 10- 13	a) 1 b) 1	NR	a) 0.6 b) 0.6	c) Diflufenican: 0.12, flufenacet: 0.24 d) Diflufenican: 0.12, flufenacet: 0.24	200-400	NR	Autumn use only

8.2 Metabolites considered in the assessment

Table 8.2-1: Metabolites of prosulfocarb potentially relevant for exposure assessment

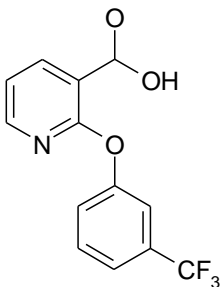
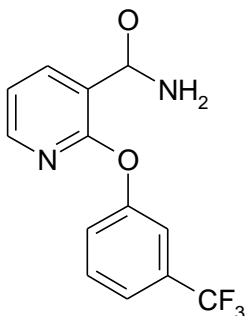
Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
Prosulfocarb sulfoxide	267.4		Soil: 6.8%	PEC _{gw} : leaching potential to groundwater PEC _{soil} : risk to soil organisms PEC _{sw/sed} : risk to aquatic organisms

Review Comments:

The prosulfocarb sulfoxide is a metabolite of prosulfocarb forming in soil but not in water or sediment. According to information included in the DAR B9 2005, no degradation products were detected in either hydrolysis or photolysis studies conducted in water. No metabolite of prosulfocarb reached significant levels in the water/sediment study (<0.8%) at any time. Thus, for surface water the risk assessment for prosulfocarb sulfoxide is not required.

In the DAR for prosulfocarb sulfoxide the PEC_{soil} were not calculated. Taking to consideration that it is soil metabolite, and high toxicity of prosulfocarb to soil organism, the prosulfocarb sulfoxide was included in the risk assessment of GLOB1912H.

Table 8.2-2: Metabolites of diflufenican potentially relevant for exposure assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
AE B107137	283		Soil: 16.8% Water: 32.6% Sediment: 13.3%	PEC _{gw} : leaching potential to groundwater PEC _{soil} : risk to soil organisms PEC _{sw/sed} : risk to aquatic organisms
AE 0542291	282		Soil: 26.3%	PEC _{gw} : leaching potential to groundwater PEC _{soil} : risk to soil organisms PEC _{sw/sed} : risk to aquatic organisms

8.3 Rate of degradation in soil (KCP 9.1.1)

Studies on degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

8.3.1.1 Prosulfocarb and its metabolites

Table 8.3-1: Summary of aerobic degradation rates for prosulfocarb - laboratory studies

Prosulfocarb, Laboratory studies, aerobic conditions										
Soil name	Soil type	pH	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Iowa	Silty clay loam	4.8	22	26	38.4 (Q10 = 2.2) 41.6 (Q10 = 2.58)	128	40.3	0.97	SFO	Y, EFSA, 2007
Heavy loamy sand	Loamy sand	5.7	21.5	9.6	11 (Q10 = 2.2) 9.73 (Q10 = 2.58)	35	9.5	0.84	SFO	Y, EFSA, 2007
Medium loamy sand	Loamy sand	5.4	21.5	9.6	22 (Q10 = 2.2) 19.36 (Q10 = 2.58)	74	18.9	0.89	SFO	Y, EFSA, 2007
Gartenacker	Silt loam	7.0	20	49.8	6.3	21	6.3	0.955	SFO	Y, EFSA, 2007
18 Acres	Sandy clay loam	6.5	20	33.3	6.7	22	6.7	0.979	SFO	Y, EFSA, 2007
Marsillargues	Silty clay loam	7.5	20	30.9	9.3	31	9.3	0.937	SFO	Y, EFSA, 2007
Geometric mean (n=6, Q10 = 2.58)							11.9			
pH-dependency: y/n							no			

Table 8.3-2: Summary of aerobic degradation rates for prosulfocarb sulfoxide - laboratory studies

Prosulfocarb sulfoxide, Laboratory studies, aerobic conditions										
Soil name	Soil type	pH	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
18 Acres	Sandy clay loam	4.8	20	32.2	2.7	8.8	2.7	0.99	SFO	Y, EFSA, 2007
Gartenacker	Loam	7.0	20	44.0	1.5	5.2	1.6	0.99	SFO	Y, EFSA, 2007
Marsillargues	Silty clay loam	7.7	20	27.6	3.9	13.0	3.9	0.99	SFO	Y, EFSA, 2007
Geometric mean (n=3)							2.5			
pH-dependency: y/n							no			

8.3.1.2 Diflufenican and its metabolites

Table 8.3-3: Summary of aerobic degradation rates for diflufenican - laboratory studies

Diflufenican, Laboratory studies, aerobic conditions										
Soil name	Soil type	pH	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
-	Sandy loam	7.7	22	75% of 0.33 bar	248.5	825.5	237.9	0.9980	SFO	Y, EFSA, 2007
-	Clay loam	6.6	22	75% of 0.33 bar	139.5	463.4	119.9	0.9967	SFO	Y, EFSA, 2007
-	Clay loam	6.5	20	45	232.6	772.7	193.5	0.9954	SFO	Y, EFSA, 2007
-	Clay loam	6.5	20	45	206.0	684.3	172.1	0.9975	SFO	Y, EFSA, 2007
-	Clay loam	6.5	20	45	176.3	585.8	147.3	0.9967	SFO	Y, EFSA, 2007
-	Silty clay loam	7.5	20	45	44.3	147.2	44.3	0.9819	SFO	Y, EFSA, 2007
-	Sandy loam 1	5.5	20	45	129.3	429.5	129.3	0.9836	SFO	Y, EFSA, 2007
-	Sandy loam 2	6.9	20	45	89.8	298.3	89.8	0.9890	SFO	Y, EFSA, 2007
-	Sandy loam 2	6.9	10	45	204.4	679.0			SFO	Y, EFSA, 2007

Diflufenican, Laboratory studies, aerobic conditions										
Soil name	Soil type	pH	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Geometric mean/Median (n=8)							128/138.3			
pH-dependency: y/n							no			

Table 8.3-4: Summary of aerobic degradation rates for AE B107137 - laboratory studies

AE B107137, Laboratory studies, aerobic conditions										
Soil name	Soil type	pH	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
-	Silt loam 1	7.0	20	45	9.1	30.2	7.5	0.9919	SFO	Y, EFSA, 2007
-	Sandy loam	6.2	20	45	17.9	59.5	13.9	0.9868	SFO	Y, EFSA, 2007
-	Silt loam 2	7.4	20	45	14.5	48.1	10.4	0.9959	SFO	Y, EFSA, 2007
Geometric mean/Median (n=3)							10.3/10.4			
pH-dependency: y/n							no			

Table 8.3-5: Summary of aerobic degradation rates for AE 0542291 - laboratory studies

AE 0542291, Laboratory studies, aerobic conditions										
Soil name	Soil type	pH	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
-	Silt loam 1	7.0	20	45	13.6	45.2	11.1	0.987	SFO	Y, EFSA, 2007
-	Sandy loam	6.2	20	45	58.7	194.9	45.7	0.999	SFO	Y, EFSA, 2007
-	Silt loam 2	7.4	20	45	33.2	110.2	23.8	0.991	SFO	Y, EFSA, 2007
Geometric mean/Median (n=3)							22.9/23.8			
pH-dependency: y/n							no			

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

8.3.2.1 Prosulfocarb and its metabolites

Table 8.3-6: Summary of anaerobic degradation rates for prosulfocarb - laboratory studies

Prosulfocarb, Laboratory studies, anaerobic conditions									
Soil name	Soil type	pH	t.°C	DT50 (d)	DT90 (d)		Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
-	Silty clay loam	4.8	Not reported	96	221	Indicative values based on only 4 data points	0.95	SFO	Y, EFSA, 2007

8.3.2.2 Diflufenican and its metabolites

EFSA, 2007:

Two degradation studies under dark anaerobic conditions were performed with 2,4-difluorophenyl and 3-trifluorophenyl labelled diflufenican (one soil: pH 6.5, OM 3.1 %, clay 23.75 %) and with pyridine labelled diflufenican (one soil: pH 7.7, OM 3.6 %, clay 15.1 %). Degradation of diflufenican was seen to be relatively slow under anaerobic conditions (DT₅₀ = 87.7 d - 400 d). Degradation of AE B107137 was also investigated under anaerobic conditions. It was shown to be very high persistent under these conditions (DT₅₀ = 413 d). The transformation product 2,4-difluoroaniline (max. 34.35 % AR after 272 d) was identified as a major anaerobic metabolite.

8.4 Field studies (KCP 9.1.1.2)

8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)

8.4.1.1 Prosulfocarb and its metabolites

A summary of the results of the field soil dissipation studies available in the EU review of prosulfocarb (EFSA, 2007) is given in the table below. However, based on the rapid degradation of prosulfocarb and the metabolite prosulfocarb sulfoxide in the laboratory studies (DegDT₅₀ < 60 d and DegDT₉₀ < 200 d), no field soil dissipation studies are required.

Table 8.4-1: Summary of aerobic degradation rates for prosulfocarb - field studies

Prosulfocarb, Field studies – Triggering endpoints								
Soil type	Location	pH	Depth (cm)	DissT50 (d) actual	DT90 (d) actual	St. (x ²)	Method of calculation	Evaluated on EU level y/n/ Reference
Sand (bare soil)	Speyer, Germany	6.4	25	6.5	22	0.83	SFO	Y, EFSA, 2007
Loam/sandy loam (bare)	Varendorf, Germany	6.7	10	9.9	33	0.99	SFO	Y, EFSA, 2007

Prosulfocarb, Field studies – Triggering endpoints								
Soil type	Location	pH	Depth (cm)	DissT50 (d) actual	DT90 (d) actual	St. (σ^2)	Method of calculation	Evaluated on EU level y/n/ Reference
soil)								
Loam/sandy loam (bare soil)	Varendorf, Germany	6.7	10	10	33	0.98	SFO	Y, EFSA, 2007
Clay loam (bare soil)	Hernigersdorf, Germany	6.8	30	11	35	0.98	SFO	Y, EFSA, 2007
Silt clay loam (bare soil)	Romerberg, Germany	7.4	10	13	48	0.94	SFO	Y, EFSA, 2007
Maximum (n=5)				13	48			

8.4.1.2 Diflufenican and its metabolites

Triggering endpoints

Table 8.4-2: Summary of aerobic degradation rates for diflufenican - field studies: Triggering endpoints

Diflufenican, Field studies – Triggering endpoints								
Soil type	Location	pH	Depth (cm)	DissT50 (d) actual	DT90 (d) actual	St. (σ^2)	Method of calculation	Evaluated on EU level y/n/ Reference
Loamy sand (b)	UK	5.8	30	621	2063	0.493	SFO	Y, EFSA, 2007
Sandy silt loam I	France	7.1	30	241	801	0.796	SFO	Y, EFSA, 2007
Sandy loam (b)	Netherlands	6.3	30	389	1292	0.495	SFO	Y, EFSA, 2007
Clay (b)	Spain	7.6	30	236	784	0.728	SFO	Y, EFSA, 2007
Clay loam (b)	Italy	6.9	30	224	744	0.748	SFO	Y, EFSA, 2007
Maximum (n=5)				621	2063			

Modelling endpoints

Table 8.4-3: Summary of aerobic degradation rates for diflufenican - field studies: Modelling endpoints

Diflufenican, Field studies – Modelling endpoints					
Soil type	Location	pH	Depth (cm)	DT50 (d) 20°C, pF2	Evaluated on EU level y/n/ Reference
Loamy sand (b)	UK	5.8	30	282.0	Y, EFSA, 2007

Diflufenican, Field studies – Modelling endpoints					
Soil type	Location	pH	Depth (cm)	DT50 (d) 20°C, pF2	Evaluated on EU level y/n/ Reference
Sandy silt loam I	France	7.1	30	130.0	Y, EFSA, 2007
Sandy loam (b)	Netherlands	6.3	30	199.5	Y, EFSA, 2007
Clay (b)	Spain	7.6	30	122.2	Y, EFSA, 2007
Clay loam (b)	Italy	6.9	30	103.4	Y, EFSA, 2007
Geometric mean/median (n=5)				156/130*	
pH-dependency y/n				no	

* Q10 of 2.2 assumed during normalization

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

8.4.2.1 Prosulfocarb

No data or assessment is provided. The kinetic evaluation of the aerobic laboratory degradation data, for prosulfocarb and prosulfocarb sulfoxide indicate that both substances degrade rapidly, in all soils, at 20°C and pF2. In all soils tested, the DegT_{50,lab} for parent and metabolites was determined to be less than 60 days and the corresponding DegT_{90,lab} were less than 200 days. Therefore soil accumulation studies are not required.

8.4.2.2 Diflufenican

Maximum accumulation factor = 2.53

8.5 Mobility in soil (KCP 9.1.2)

Studies on mobility in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

8.5.1 Prosulfocarb and its metabolites

Table 8.5-1: Summary of soil adsorption/desorption for prosulfocarb

Prosulfocarb							
Soil name	Soil type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
LUFA	Sand	0.5	6.0	32.8	1367	1.0	Y, EFSA, 2007 + Addendum

Prosulfocarb									
Soil name	Soil type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)		1/n (-)		Evaluated on EU level y/n/ Reference
									to DAR
Itingen	Clay loam	2.4	7.3	11.7	2339		0.90		Y, EFSA, 2007 + Addendum to DAR
Borstel	Loamy sand	1.00	5.14	27.6	2760		0.92		Y, EFSA, 2007 + Addendum to DAR
18 Acres	Sandy clay loam	3.25	5.6	56.7	1743		0.92		Y, EFSA, 2007 + Addendum to DAR
Vetroz	Loam	3.49	7.3	54.1	1551		0.89		Y, EFSA, 2007 + Addendum to DAR
Les Evouettes	Silt loam	1.8	5.6	24.7	1372	1420 (geomean)	0.97	0.93 (geomean)	Y, EFSA, 2007 + Addendum to DAR
Les Evouettes	Silt loam	2.55	7.2	37.5	1469		0.89		Y, EFSA, 2007 + Addendum to DAR
Geometric mean (n=6)					1799		-		
Arithmetic mean (n=6)					-		0.93		
pH-dependency y/n					no				

Table 8.5-2: Summary of soil adsorption/desorption for prosulfocarb sulfoxide

Prosulfocarb sulfoxide							
Soil Name	Soil Type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
18 Acres	Sandy clay loam	2.9	5.9	1.98	68	0.90	Y, EFSA, 2007
Gartenacker	Loam	2.0	7.1	1.02	50	0.91	Y, EFSA, 2007
Wisborough Green	Silty clay loam	2.9	4.8	1.50	52	0.91	Y, EFSA, 2007
Geometric mean (n=3)					56.1	-	
Arithmetic mean (n=3)					-	0.91	

Prosulfocarb sulfoxide							
Soil Name	Soil Type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
pH-dependency y/n					no		

8.5.2 Diflufenican and its metabolites

Table 8.5-3: Summary of soil adsorption/desorption for diflufenican

Diflufenican							
Soil name	Soil type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
-	Sandy loam	2.09	7.7	33.9	1622	0.875	Y, EFSA, 2007
-	Loamy sand	0.75	6.6	13.5	1800	0.917	Y, EFSA, 2007
-	Clay loam	1.68	6.6	39.8	2369	0.934	Y, EFSA, 2007
-	Silty clay loam	2.26	6.8	48.9	2164	0.923	Y, EFSA, 2007
Shelley Field	Clay loam	2.4	6.2	98.82	4118	0.901	Y, EFSA, 2007
Kissendorf	Silt loam	1.4	6.7	46.28	3306	0.897	Y, EFSA, 2007
Manningtree	Sandy loam	3.6	5.3	267.51	7431	0.991	Y, EFSA, 2007
Santilly	Loam	0.9	7.0	39.86	4428	0.940	Y, EFSA, 2007
Lleida	Clay loam	2.9	8.0	88.91	3066	0.917	Y, EFSA, 2007
Chazay	Clay loam	1.9	6.6	73.49	3868	0.879	Y, EFSA, 2007
Geomean (n=10)					3091	-	
Arithmetic mean (n=10)					-	0.917	
pH-dependency y/n					no		

Table 8.5-4: Summary of soil adsorption/desorption for AE B107137

AE B107137							
Soil Name	Soil Type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
-	Clay loam	1.9	7.0	0.22	12	0.72	Y, EFSA, 2007
-	Sand	1.6	5.8	0.11	7	0.99	Y, EFSA, 2007
-	Clay loam	4.7	7.6	0.38	8	0.54	Y, EFSA, 2007
-	Sandy	1.8	6.0	0.42	23	0.68	Y, EFSA, 2007

AE B107137							
Soil Name	Soil Type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
	loam						
Geomean (n=4)					11	-	
Arithmetic mean (n=4)					-	0.73	
pH-dependency y/n					no		

Table 8.5-5: Summary of soil adsorption/desorption for AE 0542291

AE 0542291							
Soil Name	Soil Type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
-	Sandy loam	0.8	6.0	1.3	160	0.80	Y, EFSA, 2007
-	Sandy loam	1.2	5.3	1.5	127	0.84	Y, EFSA, 2007
-	Clay loam	2.6	7.0	3.6	137	0.77	Y, EFSA, 2007
-	Clay	3.9	6.0	4.0	103	0.85	Y, EFSA, 2007
Geomean (n=4)					130	-	
Arithmetic mean (n=4)					-	0.81	
pH-dependency y/n					no		

8.5.3 Column leaching (KCP 9.1.2.1)

8.5.3.1 Prosulfocarb

No reliable study, as the LOQ in the available study for the leachate was high at 5 µg/L, however there is no data gap as results from adequate soil batch adsorption studies are available. Leachate: < 5 µg/L (< 0.64% of applied). The result is only considered as supportive information. (EFSA, 2007)

8.5.3.2 Diflufenican

Not submitted, not required. (EFSA, 2007)

8.5.4 Lysimeter studies (KCP 9.1.2.2)

8.5.4.1 Prosulfocarb

No studies available, not required.

8.5.4.2 Diflufenican

EFSA, 2007:

Location: Germany (Bruhl, Schwemmlöb)

Soil properties: pH = 7.7, OC = 1.05

Dates of application: 3rd December 1990

Crop: 1st year winter wheat, 2nd year barley, final green mustard

Interception estimated: none (application pre-emergent)

Number of applications: lysimeter 219 1 application each year, lysimeter 220 1 application 1st year

Duration: 2 years

Application rate: 185 g a.s./ha/year (nominal)

Average annual rainfall and irrigation: 853 mm

Average annual leachate volume: 325 mm

% radioactivity in leachate (max/year): 0.014% AR 1st year, 0.117% AR 2nd year

Individual annual average concentrations: 1st year 0.003 µg/L and 2nd year < 0.003 µg/L active substance, < 0.003 µg/L metabolites AE B10737 and AE 0542291

Unidentified radioactivity: total max 0.01 µg/L parent equivalents

8.5.5 Field leaching studies (KCP 9.1.2.3)

8.5.5.1 Prosulfocarb

No studies available, not required.

8.5.5.2 Diflufenican

Please refer to 8.5.5.2.

8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)

Studies on degradation in water/sediment systems with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

8.6.1 Prosulfocarb and its metabolites

Table 8.6-1: Summary of degradation in water/sediment of prosulfocarb

Prosulfocarb Distribution (max. water/sediment 84.1/80.4% after 0/14 days)										
Water/sediment system	pH water / sed.	DegT50 whole syst. (d)	DegT90 whole syst. (d)	Kinetic, Fit	DissT50 water (d)	DissT90 water (d)	Kinetic, Fit	DissT50 sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/ Reference
Old Basin	7.9/7.5	381/331	Too long to	DFOP SFO	0.6	13.9	DFOP SFO	Not determine	-	Y, EFSA, 2007

Prosulfocarb Distribution (max. water/sediment 84.1/80.4% after 0/14 days)										
Water/sediment system	pH water / sed.	DegT50 whole syst. (d)	DegT90 whole syst. (d)	Kinetic, Fit	DissT50 water (d)	DissT90 water (d)	Kinetic, Fit	DissT50 sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/ Reference
			predict					d		
Virginia Water	7.9/7.2	147 139	Too long to predict	DFOP SFO	1.5	51.1	DFOP SFO	Not determined	-	Y, EFSA, 2007
Geometric mean (n=2)		214	-		0.95	26.6		-		

Table 8.6-2: Summary of degradation in water/sediment of prosulfocarb sulfoxide

Prosulfocarb sulfoxide Distribution								
Water/sediment system	pH water/ sed.	DegT50 whole syst. (d)	DegT90 whole syst. (d)	Kinetic, Fit	DissT50 water (d)	DissT90 water (d)	Kinetic, Fit	Evaluated on EU level y/n/ Reference
Pond	8.3/7.2	3.69	12.27	SFO	3.02	10.0	SFO	Y, EFSA, 2007 Addendum, April 2013
River	8.3/7.3	3.32	11.02	SFO	2.82	9.38	SFO	Y, EFSA, 2007 Addendum, April 2013
Geometric mean (n=2)		3.50	11.6		2.92	9.69		

Table 8.6-3: Summary of observed metabolites

Prosulfocarb sulfoxide Water/sediment system	Max. in water/sediment 1% after 107 d	Y, EFSA, 2007
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8.6.2 Diflufenican and its metabolites

Table 8.6-4: Summary of degradation in water/sediment of diflufenican

Diflufenican Distribution (max. water/sediment 74.4% after 14 days)										
Water/sediment system	pH water/ sed.	DegT50 whole syst. (d)	DegT90 whole syst. (d)	Kinetic, Fit	DissT50 water (d)	DissT90 water (d)	Kinetic, Fit	DissT50 sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/ Reference
Unter Widdersheim	8.2/7.5	90	-	SFO, 076	n.a.	n.a.	n.a.	n.a.	n.a.	Y, EFSA, 2007

Diflufenican Distribution (max. water/sediment 74.4% after 14 days)										
Water/sediment system	pH water/sed.	DegT50 whole syst. (d)	DegT90 whole syst. (d)	Kinetic, Fit	DissT50 water (d)	DissT90 water (d)	Kinetic, Fit	DissT50 sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/Reference
Bickenbach	8.2/7.8	154	-	SFO, 0.77	n.a.	n.a.	n.a.	n.a.	n.a.	Y, EFSA, 2007
Clay, UK	7.8/6.3	345	-	SFO, 0.82	n.a.	n.a.	n.a.	n.a.	n.a.	Y, EFSA, 2007
Sand, UK	6.8/5.4	195	-	SFO, 0.96	n.a.	n.a.	n.a.	n.a.	n.a.	Y, EFSA, 2007
Geometric mean (n=4)		175	-		-	-		-		

n.a.: no reliable value available

Table 8.6-5: Summary of observed metabolites

AE B107137 Water/sediment system	Max. in water/sediment 32.6/13.3% after 30 d	Y, EFSA, 2007
AE C522392 Water/sediment system	Max. in water/sediment 6.1/1.0% after 30/59 d	Y, EFSA, 2007

8.7 Predicted Environmental Concentrations in soil (PEC_{soil}) (KCP 9.1.3)

8.7.1 Justification for new endpoints

-

8.7.2 Active substance(s) and relevant metabolite(s)

Review Comments:

The PEC_{soil} calculations for prosulfocarb, diflufenican, their metabolites and for formulation were provided by the Applicant and are considered acceptable. The EU agreed endpoints were used for PEC_{soil} calculations of prosulfocarb, diflufenican and their metabolites. For diflufenican in calculations of PEC_{soil} the accumulation factor of 2.53 from the EU review was considered.

Due to cumulation of diflufenican in the field, additionally the PEC_{soil} accumulation of metabolites AE B107137 and AE 0542291 were calculated by zRMS.

The PEC_{soil} reported below can be used for the risk assessment of the non-target organisms. Please refer to Section B9.

Table 8.7-1: Input parameters related to application for PEC_{soil} calculations

Use No.	1, 3, 5, 7	2, 4, 6, 8
Crop	Winter cereals, potato, sunflower	Winter cereals, potato, sunflower
Application rate (g as/ha)	Prosulfocarb: 2134 Diflufenican: 44.8	Prosulfocarb: 2001 Diflufenican: 42.0
Number of applications/interval	1/-	1/-
Crop interception (%)	0	0
Depth of soil layer (relevant for plateau concentration) (cm)	5 cm (no tillage)/20 (tillage; plateau conc.)	5 cm (no tillage)/20 (tillage; plateau conc.)

Table 8.7-2: Input parameter for active substance(s) and relevant metabolite(s) for PEC_{soil} calculation

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
Prosulfocarb	251.6	-	13 d (Maximum field study, not normalized)	Y, EFSA, 2007

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
Prosulfocarb sulfoxide	267.4	6.8	3.9 (Maximum laboratory study, not normalized)	Y, EFSA, 2007
Diflufenican	394	-	621 (Maximum, field study, not normalized)	Y, EFSA, 2007
AE B107137	283	16.8	17.9 (Maximum, laboratory study, not normalized)	Y, EFSA, 2007
AE 0542291	282	26.3	58.7 (Maximum, laboratory study, not normalized)	Y, EFSA, 2007

8.7.2.1 Prosulfocarb and its metabolites

Table 8.7-3: PEC_{soil} for prosulfocarb on winter cereals, potato and sunflower

PEC _{soil} (mg/kg)		Winter cereals, potato, sunflower			
		Single application (2134 g a.s./ha)		Single application (2001 g a.s./ha)	
		Actual	TWA	Actual	TWA
Initial		2.8453	-	2.6680	-
Short term	24h	2.6976	2.7708	2.5295	2.5981
	2d	2.5575	2.6989	2.3981	2.5307
	4d	2.2988	2.5624	2.1556	2.4027
Long term	7d	1.9590	2.3747	1.8369	2.2267
	14d	1.3488	2.0048	1.2647	1.8799
	21d	0.9287	1.7118	0.8708	1.6051
	28d	0.6394	1.4776	0.5995	1.3855
	50d	0.1978	0.9931	0.1855	0.9312
	100d	0.0138	0.5311	0.0129	0.4980
Plateau concentration (20 cm)		Not calculated; DT ₉₀ < 365 d			
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})					

PEC_{soil} of metabolites

Table 8.7-4: PEC_{soil} for prosulfocarb sulfoxide on winter cereals, potato and sunflower

PEC _{soil} (mg/kg)		Winter cereals, potato, sunflower			
		Single application (2134 g a.s./ha)		Single application (2001 g a.s./ha)	
		Actual	TWA	Actual	TWA

Initial		0.2056	-	0.1928	-
Short term	24h	0.1614	0.1884	0.1614	0.1767
	2d	0.1351	0.1731	0.1351	0.1623
	4d	0.0947	0.1472	0.0947	0.1380
Long term	7d	0.0556	0.1177	0.0556	0.1103
	14d	0.0160	0.0758	0.0160	0.0711
	21d	0.0046	0.0538	0.0046	0.0504
	28d	0.0013	0.0410	0.0013	0.0385
	50d	0.0000	0.0231	0.0000	0.0217
	100d	0.0000	0.0116	0.0000	0.0108
Plateau concentration (20 cm)		Not calculated; DT ₉₀ < 365 d			
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})					

8.7.2.2 Diflufenican and its metabolites

Table 8.7-5: PEC_{soil} for diflufenican on winter cereals, potato and sunflower

PEC _{soil} (mg/kg)		Winter cereals, potato, sunflower			
		Single application (44.8 g a.s./ha)		Single application (42.0 g a.s./ha)	
		Actual	TWA	Actual	TWA
Initial		0.0597	-	0.0560	-
Short term	24h	0.0597	0.0597	0.0559	0.0560
	2d	0.0596	0.0597	0.0559	0.0559
	4d	0.0595	0.0596	0.0558	0.0559
Long term	7d	0.0593	0.0595	0.0556	0.0558
	14d	0.0588	0.0593	0.0551	0.0556
	21d	0.0583	0.0590	0.0547	0.0553
	28d	0.0579	0.0588	0.0543	0.0551
	50d	0.0565	0.0581	0.0530	0.0545
	100d	0.0534	0.0565	0.0501	0.0530
Plateau concentration (20 cm)		0.0297	-	0.0278	-
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		0.0894	-	0.0838	-

Table 8.7-6: PEC_{soil} for diflufenican on winter cereals, potato and sunflower taking into account the accumulation factor of 2.53 from the EU review

PEC _{soil} (mg/kg)		Winter cereals, potato, sunflower			
		Single application (44.8 g a.s./ha)		Single application (42.0 g a.s./ha)	
		Actual	TWA	Actual	TWA
Initial		0.1510	-	0.1417	-
Short term	24h	0.1510	0.1510	0.1415	0.1416

Long term	2d	0.1508	0.1510	0.1414	0.1415
	4d	0.1505	0.1508	0.1410	0.1414
	7d	0.1500	0.1505	0.1406	0.1411
	14d	0.1488	0.1500	0.1395	0.1406
	21d	0.1475	0.1493	0.1384	0.1400
	28d	0.1465	0.1488	0.1373	0.1395
	50d	0.1429	0.1470	0.1340	0.1378
	100d	0.1351	0.1429	0.1267	0.1341

PEC_{soil} of metabolites

Table 8.7-7: PEC_{soil} for AE B107137 on winter cereals, potato and sunflower

PEC _{soil} (mg/kg)		Winter cereals, potato, sunflower			
		Single application (44.8 g a.s./ha)		Single application (42.0 g a.s./ha)	
		Actual	TWA	Actual	TWA
Initial		0.0215	-	0.0202	-
Short term	24h	0.0207	0.0211	0.0194	0.0198
	2d	0.0199	0.0207	0.0187	0.0194
	4d	0.0184	0.0200	0.0173	0.0187
Long term	7d	0.0164	0.0189	0.0154	0.0177
	14d	0.0125	0.0166	0.0117	0.0156
	21d	0.0096	0.0147	0.0090	0.0138
	28d	0.0073	0.0131	0.0068	0.0123
	50d	0.0031	0.0095	0.0029	0.0089
	100d	0.0004	0.0054	0.0004	0.0051
PEC _{accumulation} calculated with factor of 2.53		0.0544	-	0.0511	-

Table 8.7-8: PEC_{soil} for AE 0542291 on winter cereals, potato and sunflower

PEC _{soil} (mg/kg)		Winter cereals, potato, sunflower			
		Single application (44.8 g a.s./ha)		Single application (42.0 g a.s./ha)	
		Actual	TWA	Actual	TWA
Initial		0.0336	-	0.0315	-
Short term	24h	0.0332	0.0334	0.0311	0.0313
	2d	0.0328	0.0332	0.0308	0.0311
	4d	0.0321	0.0328	0.0300	0.0308
Long term	7d	0.0309	0.0323	0.0290	0.0302
	14d	0.0285	0.0310	0.0267	0.0290
	21d	0.0262	0.0298	0.0246	0.0279
	28d	0.0241	0.0286	0.0226	0.0268

	50d	0.0186	0.0254	0.0175	0.0238
	100d	0.0103	0.0197	0.0097	0.0185
PEC _{accumulation} calculated with factor of 2.53		0.0850	-	0.0797	-

8.7.2.3 PEC_{soil} of GLOB1912H

Table 8.7-9: PEC_{soil} for GLOB1912H on winter cereals, potato and sunflower

Active substance/ reparation	Application rate (g/ha)	PEC _{act} (mg/kg)	PEC _{two21 d} (mg/kg)	Tillage depth (cm)	PEC _{soil,plateau} (mg/kg)	PEC _{accu} = PEC _{act} + PEC _{soil,plateau} (mg/kg)
GLOB1912H	3231	4.3080	4.2579	5	-	-
	3029	4.0387	3.9451	5	-	-

8.8 Predicted Environmental Concentrations in groundwater (PEC_{gw}) (KCP 9.2.4)

8.8.1 Justification for new endpoints

For the Koc and DT50 in soil, the geometric mean was used in accordance with EFSA Journal 2014;12(5):3662.

The values for calculating the DT₅₀ of prosulfocarb in soil were renormalised using a Q₁₀ of 2.58.

Review Comments:

The PEC_{GW} calculations for prosulfocarb, diflufenican and their metabolites were provided by the Applicant and are considered acceptable.

According FOCUS DG SANTE for active substances and their relevant metabolites PEC_{GW} calculations after 1 January 2022 should be performed with new versions of models: FOCUS PEARL 5.5.5 and FOCUS PELMO 6.6.4. Nevertheless, as submission date is November 2021, thus the calculation performed with FOCUS MACRO 5.5.4, FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3 were accepted. The EU agreed endpoints were used. Geometric mean K_{foc} and K_{fom} (instead of an arithmetic mean K_{foc} and K_{fom}) for all compounds were derived from the datasets presented in the EFSA Scientific Report (2007) 122, 1-84 and EFSA Scientific Report (2007) 111, 1-81 for consistency with current EU Guidance [EFSA (2014): EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3362].

According Polish requirements for each crop the appropriate for Poland scenarios must be included (Châteaudun, Hamburg, Kremsmünster). For sunflower none of the required scenarios exist. Nevertheless, for Jura Max, no additional calculations are necessary for groundwater due to the very low PEC_{gw} values and pre-emergent use.

The PEC_{GW} of prosulfocarb (80th percentile) at 1 m depth following uses on cereals, potatoes and sunflower, were less than 0.001 µg/L in all scenarios. The potential for the metabolite prosulfocarb sulfoxide to leach to ground water has been assessed using the same approach. The PEC_{GW} of Prosulfocarb sulfoxide were less than 0.001 µg/L in all scenarios.

The PEC_{GW} of diflufenican (80th percentile) at 1 m depth following uses on cereals, potatoes and sunflower, were less than 0.001 µg/L in all scenarios. The potential for the metabolites AE 0542291 and AE B107137 to leach to ground water has been assessed using the same approach. The PEC_{GW} of AE 0542291 and AE B107137 were less than 0.001 µg/L in all scenarios.

In conclusion, the results demonstrate that Jura Max can be applied safely according to the recommended use patterns without risk of prosulfocarb, diflufenican and their metabolites exceeding acceptable levels in groundwater.

8.8.2 Active substance(s) and relevant metabolite(s) (KCP 9.2.4.1)

Table 8.8-1: Input parameters related to application for PEC_{gw} calculations

Use No.	1 (covering 2)	3 (covering 4)	5 (covering 6)	7 (covering 8)
Crop	Winter cereals	Winter cereals	Potato	Sunflower
Application rate (g as/ha)	Prosulfocarb: 2134 Diflufenican: 44.8	Prosulfocarb: 2134 Diflufenican: 44.8	Prosulfocarb: 2134 Diflufenican: 44.8	Prosulfocarb: 2134 Diflufenican: 44.8
Number of applications/interval (d)	1/-	1/-	1/-	1/-
Relative application date (PEARL & PELMO)	7 days before emergence	7 days after emergence	7 days before emergence	7 days before emergence
Absolute application date (MACRO)	13 Oct (286)*	27 Oct (300)*	8 Apr (98)*	N/R**
Crop interception (%)	0	0	0	0
Frequency of application	annual	annual	annual	annual
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3, FOCUS MACRO v5.5.4			

* proposed in AppDate version 3.06

** crop does not exist in Chateaudun scenario

8.8.2.1 Prosulfocarb and its metabolites

Table 8.8-2: Input parameters related to active substance prosulfocarb and metabolite prosulfocarb sulfoxide for PEC_{gw} calculations

Compound	Prosulfocarb	Prosulfocarb sulfoxide	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	251.4	267.4	Y, EFSA, 2007
Water solubility (mg/L):	13.2 (at 20°C) 26.4 (at 30°C)	2332	Y, EFSA, 2007

Compound	Prosulfocarb	Prosulfocarb sulfoxide	Value in accordance with EU endpoint y/n/ Reference*
Saturated vapour pressure (Pa):	7.9×10^{-4} (at 20°C) 3.16×10^{-3} (at 30°C)	0	Y, EFSA, 2007
DT ₅₀ in soil (d)	12.1 (geomean, normalisation to pF2, 20°C with Q ₁₀ of 2.58, n = 6)	2.5 (geomean, normalisation to pF2, 20°C with Q ₁₀ of 2.58, n = 3)	Y, EFSA, 2007 Geometric mean used in accordance with EFSA Journal 2014;12(5):3662. Values for prosulfocarb renormalised using Q ₁₀ of 2.58.
Transformation rate	-	0.0573 (prosulfocarb → prosulfocarb sulfoxide) 0.2773 (prosulfocarb sulfoxide → sink)	Calculated ($\ln 2 / DT_{50} * f.f.$)
K _{foc} (mL/g)/K _{fom}	1799/1043 (geomean, n = 6)	56.1/32.5 (geomean, n = 3)	Y, EFSA, 2007 Addendum, March 2011 Geometric mean used in accordance with EFSA Journal 2014;12(5):3662.
1/n	0.93 (arithmetic mean, n = 6)	0.91 (arithmetic mean, n = 3)	Y, EFSA, 2007 Addendum, March 2011
Plant uptake factor	0	0	Worst case
Formation fraction	-	1.0 from parent	Y, EFSA, 2007

Table 8.8-3: PEC_{gw} for prosulfocarb and metabolite on winter cereals, potato and sunflower (with FOCUS PEARL 4.4.4)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)	
		Prosulfocarb	Prosulfocarb sulfoxide
Winter cereals (pre-emergence)	Châteaudun	0.000000	0.000000
	Hamburg	0.000000	0.000003
	Jokioinen	0.000000	0.000000
	Kremsmünster	0.000000	0.000000
	Okehampton	0.000000	0.00001
	Piacenza	0.000000	0.000003
	Porto	0.000000	0.000031
	Sevilla	0.000000	0.000000
	Thiva	0.000000	0.000000
Winter cereals (post-emergence)	Châteaudun	0.000000	0.000000
	Hamburg	0.000000	0.000002
	Jokioinen	0.000000	0.000000
	Kremsmünster	0.000000	0.000000
	Okehampton	0.000000	0.000010

	Piacenza	0.000000	0.000001
	Porto	0.000000	0.000020
	Sevilla	0.000000	0.000000
	Thiva	0.000000	0.000000
Potato	Châteaudun	0.000000	0.000000
	Hamburg	0.000000	0.000000
	Jokioinen	0.000000	0.000000
	Kremsmünster	0.000000	0.000000
	Okehampton	0.000000	0.000000
	Piacenza	0.000000	0.000000
	Porto	0.000000	0.000000
	Sevilla	0.000000	0.000000
	Thiva	0.000000	0.000000
Sunflower	Piacenza	0.000000	0.000000
	Sevilla	0.000000	0.000000

Table 8.8-4: PEC_{gw} for prosulfocarb and metabolite on winter cereals, potato and sunflower (with FOCUS PELMO 5.5.3)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)	
		Prosulfocarb	Prosulfocarb sulfoxide
Winter cereals (pre-emergence)	Châteaudun	0.000	0.000
	Hamburg	0.000	0.000
	Jokioinen	0.000	0.000
	Kremsmünster	0.000	0.000
	Okehampton	0.000	0.000
	Piacenza	0.000	0.000
	Porto	0.000	0.001
	Sevilla	0.000	0.000
	Thiva	0.000	0.000
Winter cereals (post-emergence)	Châteaudun	0.000	0.000
	Hamburg	0.000	0.000
	Jokioinen	0.000	0.000
	Kremsmünster	0.000	0.000
	Okehampton	0.000	0.000
	Piacenza	0.000	0.000
	Porto	0.000	0.001
	Sevilla	0.000	0.000
	Thiva	0.000	0.000
Potato	Châteaudun	0.000	0.000

	Hamburg	0.000	0.000
	Jokioinen	0.000	0.000
	Kremsmünster	0.000	0.000
	Okehampton	0.000	0.000
	Piacenza	0.000	0.000
	Porto	0.000	0.000
	Sevilla	0.000	0.000
	Thiva	0.000	0.000
Sunflower	Piacenza	0.000	0.000
	Sevilla	0.000	0.000

Table 8.8-5: PEC_{gw} for prosulfocarb on winter cereals, potato and sunflower (with FOCUS MACRO 5.5.4)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)
		Prosulfocarb
Winter cereals, pre-emergence	Châteaudun	0
Winter cereals, post-emergence	Châteaudun	0
Potato	Châteaudun	0

8.8.2.2 Diflufenican and its metabolites

Table 8.8-6: Input parameters related to active substance diflufenican and metabolites for PEC_{gw} calculations

Compound	Diflufenican	AE 0542291	AE B107137	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	394	282	283	Y, EFSA, 2007
Water solubility (mg/L):	0.05 (at 20°C) 0.1 (at 30°C)	100	410	Y, EFSA, 2007
Saturated vapour pressure (Pa):	4.25 x 10 ⁻⁶ (at 25°C) 1.72 x 10 ⁻⁵ (at 35°C)	10 ⁻¹⁰	10 ⁻¹⁰	Y, EFSA, 2007
DT ₅₀ in soil (d)	128 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n =8)	22.9 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n = 3)	10.3 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n =3)	Y, EFSA, 2007 Geometric mean used in accordance with EFSA Journal 2014;12(5):3662.
Transformation rate	-	0.0054	0.0054	Calculated (ln2/DT ₅₀ *f.f.)
K _{foc} (mL/g)/K _{fom}	3091/1793 (geomean, n = 10)	130/75 (geomean, n = 4)	11/6.4 (geomean, n = 4)	Y, EFSA, 2007 Geometric mean

Compound	Diflufenican	AE 0542291	AE B107137	Value in accordance with EU endpoint y/n/ Reference*
				used in accordance with EFSA Journal 2014;12(5):3662.
1/n	0.917 (arithmetic mean, n = 10)	0.81 (arithmetic mean, n = 4)	0.73 (arithmetic mean, n = 4)	Y, EFSA, 2007
Plant uptake factor	0	0	0	worst case
Formation fraction	-	1 from parent	1 from parent	Y, EFSA, 2007

Table 8.8-7: PEC_{gw} for diflufenican and metabolites on winter cereals, potato and sunflowers (with FOCUS PEARL 4.4.4)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		Diflufenican	AE 0542291	AE B107137
Winter cereals (pre-emergence)	Châteaudun	0.000000	0.000000	0.000000
	Hamburg	0.000000	0.000000	0.000041
	Jokioinen	0.000000	0.000000	0.000000
	Kremsmünster	0.000000	0.000000	0.000000
	Okehampton	0.000000	0.000000	0.000043
	Piacenza	0.000000	0.000000	0.000001
	Porto	0.000000	0.000000	0.000004
	Sevilla	0.000000	0.000000	0.000000
	Thiva	0.000000	0.000000	0.000000
Winter cereals (post-emergence)	Châteaudun	0.000000	0.000000	0.000000
	Hamburg	0.000000	0.000000	0.000031
	Jokioinen	0.000000	0.000000	0.000000
	Kremsmünster	0.000000	0.000000	0.000000
	Okehampton	0.000000	0.000000	0.000021
	Piacenza	0.000000	0.000000	0.000002
	Porto	0.000000	0.000000	0.000000
	Sevilla	0.000000	0.000000	0.000000
	Thiva	0.000000	0.000000	0.000000
Potato	Châteaudun	0.000000	0.000000	0.000000
	Hamburg	0.000000	0.000000	0.000002
	Jokioinen	0.000000	0.000000	0.000000
	Kremsmünster	0.000000	0.000000	0.000000
	Okehampton	0.000000	0.000000	0.000004
	Piacenza	0.000000	0.000000	0.000002

	Porto	0.000000	0.000000	0.000000
	Sevilla	0.000000	0.000000	0.000000
	Thiva	0.000000	0.000000	0.000000
Sunflower	Piacenza	0.000000	0.000000	0.000002
	Sevilla	0.000000	0.000000	0.000000

Table 8.8-8: PEC_{gw} for diflufenican and metabolites on winter cereals, potato and sunflower (with FOCUS PELMO 5.5.3)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		Diflufenican	AE 0542291	AE B107137
Winter cereals (pre-emergence)	Châteaudun	0.000	0.000	0.000
	Hamburg	0.000	0.000	0.000
	Jokioinen	0.000	0.000	0.000
	Kremsmünster	0.000	0.000	0.000
	Okehampton	0.000	0.000	0.000
	Piacenza	0.000	0.000	0.000
	Porto	0.000	0.000	0.000
	Sevilla	0.000	0.000	0.000
	Thiva	0.000	0.000	0.000
Winter cereals (post-emergence)	Châteaudun	0.000	0.000	0.000
	Hamburg	0.000	0.000	0.000
	Jokioinen	0.000	0.000	0.000
	Kremsmünster	0.000	0.000	0.000
	Okehampton	0.000	0.000	0.000
	Piacenza	0.000	0.000	0.000
	Porto	0.000	0.000	0.000
	Sevilla	0.000	0.000	0.000
	Thiva	0.000	0.000	0.000
Potato	Châteaudun	0.000	0.000	0.000
	Hamburg	0.000	0.000	0.000
	Jokioinen	0.000	0.000	0.000
	Kremsmünster	0.000	0.000	0.000
	Okehampton	0.000	0.000	0.000
	Piacenza	0.000	0.000	0.000
	Porto	0.000	0.000	0.000
	Sevilla	0.000	0.000	0.000
	Thiva	0.000	0.000	0.000
Sunflower	Piacenza	0.000	0.000	0.000
	Sevilla	0.000	0.000	0.000

Table 8.8-9: PEC_{gw} for diflufenican and AE 0542291 on winter cereals, potato and sunflower (with FOCUS MACRO 5.5.4)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)	
		Diflufenican	AE 0542291
Winter cereals, pre-emergence	Châteaudun	0	0
Winter cereals, post-emergence	Châteaudun	0	0
Potato	Châteaudun	0	0

8.9 Predicted Environmental Concentrations in surface water (PEC_{sw}) (KCP 9.2.5)

8.9.1 Justification for new endpoints

For the Koc and DT50 in soil, the geometric mean was used in accordance with EFSA Journal 2014;12(5):3662.

The values for calculating the DT₅₀ of prosulfocarb in soil were renormalised using a Q₁₀ of 2.58.

Review Comments:

The PEC_{SW/SED} calculations for prosulfocarb, diflufenican and its metabolites were provided by the Applicant and are considered acceptable. The calculation for prosulfocarb sulfoxide, were provided, nevertheless should be considered only as supportive data. The prosulfocarb sulfoxide is a metabolite of prosulfocarb forming in soil but not in water or sediment. According to information included in the DAR 2005, no degradation products were detected in either hydrolysis or photolysis studies conducted in water. No metabolite of prosulfocarb reached significant levels in the water/sediment study (<0.8%) at any time. Thus, for surface water the risk assessment for prosulfocarb sulfoxide is not required. The PEC_{sw} calculation presented below were left only for illustrative assessment.

For active substances and relevant metabolites PEC_{sw} calculations were performed with FOCUS STEPS 1-2 (active substances and metabolites) and FOCUS STEP 3 - 4 (prosulfocarb, its metabolite and diflufenican). Additionally for diflufenican FOCUS profiles of scenarios with a maximum PEC_{sw} above 0.1 µg/L (but below 0.42 µg/L) were analysed using EPAT v1.2. Acceptability of this approach should be consider at MSs level. For Poland EPAT is not accepted.

The EU agreed endpoints were used. Geometric mean K_{foc} and K_{fom} (instead of an arithmetic mean K_{foc} and K_{fom}) for all compounds were derived from the datasets presented in the EFSA Scientific Report (2007) 122, 1-84 and EFSA Scientific Report (2007) 111, 1-81 for consistency with current EU Guidance [EFSA (2014): EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3362].

According Polish requirements for each crop the appropriate for Poland scenarios must be included (D3, D4 and R1). For sunflower the required D3 and D4 scenarios does not exist. Thus, additional calculations for maize were performed.

The formulation PEC_{sw} calculations were accepted.

The PEC_{sw} reported below can be used for the risk assessment for aquatic organisms. Please refer to section 9.

8.9.2 Active substance(s), relevant metabolite(s) and the formulation (KCP 9.2.5)

Table 8.9-1: Input parameters related to application for PEC_{SW/SED} calculations

Plant protection product	GLOB1912H			
Use No.	1 (covering 2)	3 (covering 4)	5 (covering 6)	7 (covering 8)
Crop	Winter cereals	Winter cereals	Potato	Sunflower
Application rate (g as/ha)	Prosulfocarb: 2134 Diflufenican: 44.8	Prosulfocarb: 2134 Diflufenican: 44.8	Prosulfocarb: 2134 Diflufenican: 44.8	Prosulfocarb: 2134 Diflufenican: 44.8
Number of applications/interval (d)	1/-	1/-	1/-	1/-
Application window	October – February (relevant for STEP 1 and 2 only)	October – February (relevant for STEP 1 and 2 only)	March-May June-September (relevant for STEP 1 and 2 only)	March-May (relevant for STEP 1 and 2 only)
Application method	Ground spray	Ground spray	Ground spray	Ground spray
CAM (Chemical application method)	CAM 1 – soil linear	CAM 2 – foliar linear	CAM 1 – soil linear	CAM 1 – soil linear
Soil depth (cm)	4	4	4	4
Models used for calculation	STEPS 1-2 v 3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3, SWAN v5.0.0, EPAT v1.2			

Table 8.9-2: FOCUS Step 3 Scenario related input parameters for PEC_{sw/sed} calculations for the application of GLOB1912H

Crop	Scenario	Application window used in modelling*
Winter cereals, pre-emergence	D1	15/09 – 25/10 (258 - 288)
	D2	15/10 – 14/11 (288 – 318)
	D3	11/11 – 11/12 (315 – 345)
	D4	12/09 – 12/10 (255 – 285)
	D5	31/10 – 30/11 (304 – 334)
	D6	20/11 – 20/12 (324 – 354)
	R1	02/11 – 02/12 (306 – 336)
	R3	21/11 – 21/12 (325 – 355)
	R4	31/10 – 30/11 (304 - 334)
Winter cereals, post-emergence	D1	26/09 – 26/10 (269 - 299)
	D2	26/10 – 25/11 (299 – 329)
	D3	22/11 – 22/12 (326 – 356)
	D4	23/09 – 23/10 (266 – 296)
	D5	11/11 – 11/12 (315 – 345)
	D6	01/12 – 31/12 (335 – 365)
	R1	13/11 – 13/12 (317 – 347)

Crop	Scenario	Application window used in modelling*
Potato	R3	02/12 – 01/01 (336 – 1)
	R4	11/11 – 11/12 (315 - 345)
	D3	30/04 – 30/05 (120 – 150)
	D4	12/05 – 11/06 (132 – 162)
	D6	31/03 – 30/04 (90 – 120)
		26/07 – 25/08 (207-237)
	R1	25/04 – 25/05 (115 – 145)
	R2	05/03 – 04/04 (64-94)
	R3	31/03 – 30/04 (90 – 120)
Sunflower	D3**	25/04 – 25/05 (115 - 145)
	D4**	30/04 – 30/05 (120 - 150)
	D5	21/04 – 21/05 (111 – 141)
	R1	21/04 – 21/05 (111 – 141)
	R3	05/04 – 05/05 (95 – 125)
	R4	20/03 – 19/04 (79 - 109)

* window proposed in AppDate version 3.06

** maize used as surrogate crop

8.9.2.1 Prosulfocarb and its metabolites

Table 8.9-3: Input parameters related to active substance prosulfocarb and metabolite prosulfocarb sulfoxide for PEC_{sw/sed} calculations STEP 1/2 and 3(/4)

Compound	Prosulfocarb	Prosulfocarb sulfoxide	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	251.4	267.4	Y, EFSA, 2007
Saturated vapour pressure (Pa)	7.9 x 10 ⁻⁴ (at 20°C)	0	Y, EFSA, 2007
Water solubility (mg/L)	13.2	2332	Y, EFSA, 2007
Diffusion coefficient in water (m ² /d)	4.3 x 10 ⁻⁵	4.3 x 10 ⁻⁵	default
Diffusion coefficient in air (m ² /d)	0.43	0.43	default
K _{foc} (mL/g)	1799 (geomean, n = 6)	56.1 (geomean, n = 3)	Y, EFSA, 2007 Addendum, March 2011 Geometric mean used in accordance with EFSA Journal 2014;12(5):3662.
Freundlich Exponent 1/n	0.93 (arithmetic mean, n = 6)	0.91 (arithmetic mean, n = 3)	Y, EFSA, 2007 Addendum, March 2011
Plant Uptake	0	0	Worst case
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	0.05 (MACRO) 0.50 (PRZM)	default
DT _{50,soil} (d)	12.1 (geomean,	2.5 (geomean,	Y, EFSA, 2007

Compound	Prosulfocarb	Prosulfocarb sulfoxide	Value in accordance to EU endpoint y/n/ Reference
	normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n = 6)	normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n = 3)	Geometric mean used in accordance with EFSA Journal 2014;12(5):3662. Values for prosulfocarb renormalised using Q ₁₀ of 2.58.
DT _{50,water} (d)	1000 (default) or 331 (worst case from sediment water studies)	3.5	Y, EFSA, 2007 Addendum, April 2013
DT _{50,sed} (d)	331 (worst case from sediment water studies) or 1000 (default)	1000	Y, EFSA, 2007
DT _{50,whole system} (d)	331 (worst case from sediment water studies)	3.5	Y, EFSA, 2007 Addendum, April 2013
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 6.8 Water: Sediment: 1	Y, EFSA, 2007
Formation fraction in soil	-	1 (from parent)	Y, EFSA, 2007

Since the prosulfocarb K_{foc} is within the range 100-2000, two sets of Step 3 and 4 simulations with different water/sediment DT₅₀ inputs are required; one with the whole system DT₅₀ of 331 days applied to the water (DT₅₀ of 1000 days for sediment) (= “water degradation”) and one with the whole system DT₅₀ of 331 days applied to the sediment (DT₅₀ of 1000 days for water) (= “sediment degradation”).

At the results of Step 3, the concentrations shown are the maximum obtained from either the “water degradation” or “sediment degradation” analyses. In practice, the two different approaches can be considered equivalent. There were some small differences noted, mainly between the PEC_{sed} values, however, these have no impact on the risk assessment.

The Step 4 calculations for prosulfocarb and the metabolite prosulfocarb sulfoxide are based on the “sediment degradation” Step 3 calculations, since these are equal to or worst-case compared to the “water degradation” Step 3 calculations.

PEC_{sw/sed}

Table 8.9-4: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for prosulfocarb following single application of GLOB1912H to winter cereals (pre-emergence)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	---	228.92	-	210.74	3860
Step 2					
Northern Europe	Oct-Feb	90.77	-	87.53	1600
Southern Europe	Oct-Feb	74.13	-	71.16	1300
Step 3					

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
D1	ditch	13.66	Drainage	8.957	43.65
D1	stream	11.95	Drainage	0.5171	6.358
D2	ditch	13.68	Drainage	2.349	22.54
D2	stream	12.17	Drainage	1.937	19.88
D3	ditch	13.46	Drainage	0.5172	6.340
D4	pond	0.4659	Drainage	0.3889	3.194
D4	stream	11.68	Drainage	0.1612	2.361
D5	pond	0.4668	Drainage	0.3952	2.893
D5	stream	12.60	Drainage	0.2312	3.264
D6	ditch	13.62	Drainage	4.100	25.69
R1	pond	1.309	Runoff	1.112	10.86
R1	stream	10.28	Runoff	0.3927	7.478
R3	stream	13.92	Runoff	1.589	404.4
R4	stream	8.931	Runoff	0.3502	5.333

* single applications should be marked.

** two-time as required by ecotox

Table 8.9-5: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for prosulfocarb following single application of GLOB1912H to winter cereals (post-emergence)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	---	228.92	-	210.74	3860
Step 2					
Northern Europe	Oct-Feb	90.77	-	87.53	1600
Southern Europe	Oct-Feb	74.13	-	71.16	1300
Step 3					
D1	ditch	13.66	Drainage	9.015	44.10
D1	stream	11.95	Drainage	0.5174	6.363
D2	ditch	13.58	Drainage	1.989	19.20
D2	stream	11.02	Drainage	0.04856	0.7522
D3	ditch	13.46	Drainage	0.4924	6.101
D4	pond	0.4659	Drainage	0.3894	3.147
D4	stream	11.68	Drainage	0.1611	2.361
D5	pond	0.4673	Drainage	0.3957	2.911
D5	stream	12.60	Drainage	0.2312	3.264

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
D6	ditch	13.62	Drainage	4.100	25.70
R1	pond	1.302	Runoff	1.106	10.81
R1	stream	10.20	Runoff	0.3902	7.434
R3	stream	12.97	Runoff	0.6521	7.347
R4	stream	14.95	Runoff	0.7119	10.54

* single applications should be marked.

** twa-time as required by ecotox

Table 8.9-6: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for prosulfocarb following single application of GLOB1912H to potato

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	---	228.92	-	210.74	3860
Step 2					
Northern Europe	March-May	40.84	-	38.43	700.64
	June-Sept	40.84	-	38.43	700.64
Southern Europe	March-May	74.13	-	71.16	1300
	June-Sept	57.48	-	54.80	999.43
Step 3					
D3	ditch	11.17	Drainage	0.6116	6.856
D4	pond	0.4510	Drainage	0.3703	2.560
D4	stream	9.224	Drainage	0.02624	0.4197
D6, 1st	ditch	11.05	Drainage	0.2595	3.433
D6, 2nd	ditch	11.24	Drainage	2.039	14.57
R1	pond	0.7623	Runoff	0.6642	6.066
R1	stream	7.721	Runoff	0.3594	6.113
R2	stream	10.22	Runoff	0.3211	166.6
R3	stream	10.90	Runoff	0.6473	11.92

* single applications should be marked.

** twa-time as required by ecotox

Table 8.9-7: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for prosulfocarb following single application of GLOB1912H to sunflower

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	---	228.92	-	210.74	3860
Step 2					

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Northern Europe	March-May	40.84	-	38.43	700.64
Southern Europe	March-May	74.13	-	71.16	1300
Step 3					
D3	ditch	11.18	Drainage	0.6201	6.933
D4	pond	0.4511	Drainage	0.3725	2.836
D4	stream	9.571	Drainage	0.04068	0.6416
D5	pond	0.4512	Drainage	0.3739	2.952
D5	stream	10.10	Drainage	0.03445	0.5471
R1	pond	0.7971	Runoff	0.6949	6.393
R1	stream	7.714	Runoff	0.3640	6.620
R3	stream	10.90	Runoff	0.6579	16.87
R4	stream	15.72	Runoff	0.8717	12.81

* single applications should be marked.

** twa-time as required by ecotox

FOCUS Step 4

Step 4 calculations were done with the following mitigation measures to refine the aquatic risk assessment of the active substance:

- spray drift reduction of 50% drift reducing nozzles
- spray drift reduction by buffer zones of 5 m and 10 m

Additional Step 4 calculations were done in order to calculate PEC_{mix} in the aquatic mixture toxicity risk assessment.

Since prosulfocarb is volatile, dry deposition was implemented in the Step 4 calculations using deposition rates calculated with the UBA tool EVA 3.0 rev2h (see table below).

Table 8.9-8: Dry deposition rates for prosulfocarb in Step 4 calculations (from EVA 3.0 rev2h)

Application pattern	Spray drift scenario/interception	Time after application (hours)	Deposition rates (g/ha)			
			1 m	5 m	10 m	20 m
1 x 2134 g a.s./ha	Arable crops/0%	0-4	0.0143	0.0115	0.0087	0.0051
		4-12	0.0071	0.0057	0.0044	0.0025
		12-24	0.0036	0.0029	0.0022	0.0013

Table 8.9-9: Global maximum PEC_{sw} values for prosulfocarb, following single application of GLOB1912H to winter cereals (pre-emergence) according to the ~~southern~~ central EU zone GAP according to surface water Step 4

PEC _{sw} (µg/L)	Scenario	STEP 4 Prosulfocarb		
Nozzle reduction	Vegetative strip (m)	None	None	10
	No spray buffer (m)	5	10	10
None	D1 ditch	3.799	-	-
None	D1 stream	4.37	-	-
None	D2 ditch	3.807	-	-
None	D2 stream	4.451	-	-
None	D3 ditch	3.65	-	-
None	D4 stream	4.284	-	-
None	D5 stream	4.608	-	-
None	D6 ditch	7.401	-	-
None	R1 stream	-	-	4.600
None	R3 stream	-	-	6.354
None	R4 stream	-	-	3.640

Table 8.9-10: Global maximum PEC_{sw} values for prosulfocarb, following single application of GLOB1912H to winter cereals (post-emergence) according to the ~~southern~~ central EU zone GAP according to surface water Step 4

PEC _{sw} (µg/L)	Scenario	STEP 4 Prosulfocarb		
Nozzle reduction	Vegetative strip (m)	None	None	10
	No spray buffer (m)	5	10	10
None	D1 ditch	3.8	-	-
None	D1 stream	4.37	-	-
None	D2 ditch	3.683	-	-
None	D2 stream	4.09	-	-
None	D3 ditch	3.648	-	-
None	D4 stream	4.284	-	-
None	D5 stream	4.608	-	-
None	D6 ditch	7.401	-	-
None	R1 stream	-	-	4.564
None	R3 stream	-	-	5.840
None	R4 stream	14.95	14.95	6.748

PEC _{sw} (µg/L)	Scenario	STEP 4 Prosulfocarb		
Nozzle reduction	Vegetative strip (m)	None	None	10
	No spray buffer (m)	5	10	10
50 %		14.95	-	-
75 %		-	-	-
90 %		-	-	-

Table 8.9-11: Global maximum PEC_{sw} values for prosulfocarb, following single application of GLOB1912H to potato according to the **central** ~~southern~~ EU zone GAP according to surface water Step 4

PEC _{sw} (µg/L)	Scenario	STEP 4 Prosulfocarb		
Nozzle reduction	Vegetative strip (m)	None	None	10
	No spray buffer (m)	5	10	10
None	D3 ditch	3.662	-	-
None	D4 stream	3.937	-	-
None	D6 ditch, 1st	3.622	-	-
None	D6 ditch, 2nd	3.712	-	-
None	R1 stream	-	-	2.543
None	R2 stream	-	-	2.345
None	R3 stream	-	-	3.671

Table 8.9-12: Global maximum PEC_{sw} values for prosulfocarb, following single application of GLOB1912H to sunflower according to the **central** ~~southern~~ EU zone GAP according to surface water Step 4

PEC _{sw} (µg/L)	Scenario	STEP 4 Prosulfocarb		
Nozzle reduction	Vegetative strip (m)	None	None	10
	No spray buffer (m)	5	10	10
None	D3 ditch	3.663	-	-
None	D4 stream	4.091	-	-
None	D5 stream	4.316	-	-
None	R1 stream	-	-	2.574
None	R3 stream	-	-	4.643

PEC _{sw} (µg/L)	Scenario	STEP 4 Prosulfocarb		
Nozzle reduction	Vegetative strip (m)	None	None	10
	No spray buffer (m)	5	10	10
None	R4 stream	15.72	15.72	7.148
50 %		15.72	-	-
75 %		-	-	-
90 %		-	-	-

Metabolite of prosulfocarb

Review Comments:

The prosulfocarb sulfoxide is a metabolite of prosulfocarb forming in soil but not in water or sediment. According to information included in the DAR 2005, no degradation products were detected in either hydrolysis or photolysis studies conducted in water. No metabolite of prosulfocarb reached significant levels in the water/sediment study (<0.8%) at any time. Thus, the studies on metabolites are not required. Furthermore, according to EFSA Scientific Report (2007) 111, 1-81, for surface water the risk assessment for prosulfocarb sulfoxide is not required.

Table 8.9-13: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for prosulfocarb sulfoxide following single application to winter cereals (pre-emergence)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	---	55.12	-	13.05	30.80
Step 2					
Northern Europe	Oct-Feb	10.79	-	2.72	6.05
Southern Europe	Oct-Feb	8.65	-	2.18	4.85
Step 3					
D1	ditch	43.39	Drainage	27.24	30.71
D1	stream	28.45	Drainage	18.54	20.44
D2	ditch	81.08	Drainage	31.09	42.94
D2	stream	51.65	Drainage	18.06	19.88
D3	ditch	< 0.000001	Drainage	< 0.000001	< 0.000001
D4	pond	1.827	Drainage	1.562	1.749
D4	stream	3.376	Drainage	1.512	1.674

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
D5	pond	5.964	Drainage	4.355	5.363
D5	stream	9.050	Drainage	2.696	4.218
D6	ditch	19.55	Drainage	5.431	7.065
R1	pond	0.2618	Runoff	0.1639	0.2125
R1	stream	9.351	Runoff	0.1918	1.201
R3	stream	7.610	Runoff	0.6400	1.909
R4	stream	7.242	Runoff	0.2249	1.078

* single applications should be marked.

** twa-time as required by ecotox

Table 8.9-14: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for prosulfocarb sulfoxide following single application to winter cereals (post-emergence)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	---	55.12	-	13.05	30.80
Step 2					
Northern Europe	Oct-Feb	10.79	-	2.72	6.05
Southern Europe	Oct-Feb	8.65	-	2.18	4.85
Step 3					
D1	ditch	49.35	Drainage	33.78	39.47
D1	stream	30.94	Drainage	11.86	25.30
D2	ditch	73.44	Drainage	25.05	40.72
D2	stream	46.43	Drainage	14.50	24.31
D3	ditch	< 0.000001	Drainage	< 0.000001	< 0.000001
D4	pond	2.816	Drainage	2.401	2.614
D4	stream	5.242	Drainage	2.320	2.401
D5	pond	5.964	Drainage	4.355	5.455
D5	stream	9.050	Drainage	2.696	4.272
D6	ditch	19.42	Drainage	5.300	6.994
R1	pond	0.2601	Runoff	0.1628	0.2110
R1	stream	9.248	Runoff	0.1897	1.188
R3	stream	8.615	Runoff	0.3194	1.290
R4	stream	10.20	Runoff	0.3224	1.501

* single applications should be marked.

** twa-time as required by ecotox

Table 8.9-15: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for prosulfocarb sulfoxide following single application to potato

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	---	55.12	-	13.05	30.80
Step 2					
Northern Europe	March-May	4.37	-	1.10	2.45
	June-Sept	4.37	-	1.10	2.45
Southern Europe	March-May	8.65	-	2.18	4.85
	June-Sept	6.51	-	1.64	3.65
Step 3					
D3	ditch	< 0.000001	Drainage	< 0.000001	< 0.000001
D4	pond	0.02693	Drainage	0.02340	0.03419
D4	stream	0.04689	Drainage	0.02291	0.04325
D6, 1st	ditch	4.857	Drainage	0.5901	1.280
D6, 2nd	ditch	5.796	Drainage	1.228	1.472
R1	pond	0.3752	Runoff	0.2148	0.2588
R1	stream	7.073	Runoff	0.4369	1.176
R2	stream	7.806	Runoff	0.5723	2.590
R3	stream	11.74	Runoff	0.6668	2.438

* single applications should be marked.

** twa-time as required by ecotox

Table 8.9-16: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for prosulfocarb sulfoxide following single application to sunflower

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	---	55.12	-	13.05	30.80
Step 2					
Northern Europe	March-May	4.37	-	1.10	2.45
Southern Europe	March-May	8.65	-	2.18	4.85
Step 3					
D3	ditch	< 0.000001	Drainage	< 0.000001	< 0.000001
D4	pond	0.04099	Drainage	0.03487	0.04604
D4	stream	0.07392	Drainage	0.03368	0.04983
D5	pond	0.003939	Drainage	0.002855	0.004483
D5	stream	0.005903	Drainage	0.01771	0.003486

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
R1	pond	0.4289	Runoff	0.2498	0.2949
R1	stream	7.430	Runoff	0.4462	1.232
R3	stream	12.40	Runoff	0.5773	2.496
R4	stream	15.13	Runoff	0.8460	2.700

* single applications should be marked.

** two-time as required by ecotox

FOCUS Step 4

Step 4 calculations were done with the following mitigation measures:

- spray drift reduction of 50% drift reducing nozzles
- spray drift reduction by buffer zones of 5 m, 10 m and 20 m

Since prosulfocarb is volatile, dry deposition was implemented in the Step 4 calculations using deposition rates calculated with the UBA tool EVA 3.0 rev2h (see table below).

Table 8.9-17: Dry deposition rates for prosulfocarb in Step 4 calculations (from EVA 3.0 rev2h)

Application pattern	Spray drift scenario/interception	Time after application (hours)	Deposition rates (g/ha)			
			1 m	5 m	10 m	20 m
1 x 2134 g a.s./ha	Arable crops/0%	0-4	0.0143	0.0115	0.0087	0.0051
		4-12	0.0071	0.0057	0.0044	0.0025
		12-24	0.0036	0.0029	0.0022	0.0013

Table 8.9-18: Global maximum PEC_{sw} values for prosulfocarb sulfoxide, following single application of GLOB1912H to winter cereals (pre-emergence) according to the central southern EU zone GAP according to surface water Step 4

PEC _{sw} (µg/L)	Scenario	STEP 4 Prosulfocarb sulfoxide
Nozzle reduction	Vegetative strip (m)	None
	No spray buffer (m)	20
None	D1 ditch	43.39
50 %		43.39
75 %		-
90 %		-
None	D1 stream	28.45
50 %		28.45
75 %		-
90 %		-
None	D2 ditch	81.08

PEC _{sw} (µg/L)	Scenario	STEP 4 Prosulfocarb sulfoxide
Nozzle reduction	Vegetative strip (m)	None
	No spray buffer (m)	20
50 %		81.08
75 %		-
90 %		-
None	D2 stream	51.65
50 %		51.65
75 %		-
90 %		-
None	D6 ditch	19.55
50 %		19.55
75 %		-
90 %		-

Table 8.9-19: Global maximum PEC_{sw} values for prosulfocarb sulfoxide, following single application of GLOB1912H to winter cereals (post-emergence) according to the **central** ~~southern~~ EU zone GAP according to surface water Step 4

PEC _{sw} (µg/L)	Scenario	STEP 4 Prosulfocarb sulfoxide
Nozzle reduction	Vegetative strip (m)	None
	No spray buffer (m)	20
None	D1 ditch	-
50 %		49.35
75 %		-
90 %		-
None	D1 stream	-
50 %		30.94
75 %		-
90 %		-
None	D2 ditch	-
50 %		73.44
75 %		-
90 %		-
None	D2 stream	-
50 %		46.43

PEC _{sw} (µg/L)	Scenario	STEP 4 Prosulfocarb sulfoxide
Nozzle reduction	Vegetative strip (m)	None
	No spray buffer (m)	20
75 %	D6 ditch	-
90 %		-
None		-
50 %		19.42
75 %		-
90 %		-

Table 8.9-20: Global maximum PEC_{sw} values for prosulfocarb sulfoxide, following single application of GLOB1912H to sunflower according to the central southern EU zone GAP according to surface water Step 4

PEC _{sw} (µg/L)	Scenario	STEP 4 Prosulfocarb sulfoxide		
Nozzle reduction	Vegetative strip (m)	None	None	10
	No spray buffer (m)	5	10	10
None	R4 stream	15.13	15.13	7.148
50 %		15.13	-	-
75 %		-	-	-
90 %		-	-	-

For prosulfocarb sulfoxide, a tiered approach was followed at Step 3-4: At Tier 1, prosulfocarb sulfoxide was implemented as a normal metabolite of prosulfocarb in SWASH. However, since the true formation fraction of prosulfocarb sulfoxide in soil is uncertain, a refined simulation for prosulfocarb sulfoxide was undertaken, as a 'Tier 2', simulating the metabolite as a pseudo-parent. This approach is consistent with that previously established at EU level.

Prosulfocarb sulfoxide is a metabolite of prosulfocarb forming in soil but not in water or sediment. The maximum observed amount of prosulfocarb sulfoxide in laboratory soil degradation studies was 6.8%. The application rate of prosulfocarb was factored to account for the difference in molar mass between prosulfocarb (251.4 g/mol) and prosulfocarb sulfoxide (267.4 g/mol) and the maximum observed amount of prosulfocarb sulfoxide in soil, leading to an application rate of 154.3 g/ha for prosulfocarb sulfoxide.

In the Step 3 simulations, ground spray was considered and the application method was set to CAM-1 because prosulfocarb sulfoxide is a metabolite formed in soil but not on plants. Since spray drift is not a possible route of exposure for metabolites formed in soil, a SWAN run with 100% drift reduction was performed in order to eliminate drift entries.

The maximum amount of prosulfocarb sulfoxide was found in laboratory degradation studies at day 18

after application of the parent substance prosulfocarb. Thus, for the present calculations for prosulfocarb sulfoxide, the appropriate application window for the metabolite starts 18 days later than the respective window for the parent substance. The length of the window was set to 30 days.

The results can be found in Table 8.9-20 to 8.9-23 below.

Table 8.9-21: FOCUS Step 3 Scenario related input parameters for $PEC_{sw/sed}$ calculations for the application of GLOB1912H

Crop	Scenario	Application window used in modelling
Winter cereals, pre-emergence	D1	03/10 – 02/11 (276 - 306)
	D2	02/11 – 02/12 (306 – 336)
	D3	29/11 – 29/12 (333 – 363)
	D4	30/09 – 30/10 (273-303)
	D5	18/11 – 18/12 (322 – 352)
	D6	08/12 – 07/01 (342 – 7)
	R1	20/11 – 20/12 (324 – 354)
	R3	09/12 – 08/01 (343 – 8)
	R4	18/11 – 18/12 (322 - 352)
Winter cereals, post-emergence	D1	14/10 – 13/11 (287 - 317)
	D2	13/11 – 13/12 (317 – 347)
	D3	10/12 – 09/01 (344 – 9)
	D4	11/10 – 10/11 (284 – 314)
	D5	29/11 – 29/12 (333 – 363)
	D6	19/12 – 18/01 (353 – 18)
	R1	01/12 – 31/12 (335 – 365)
	R3	20/12 – 19/01 (354 – 19)
	R4	29/11 – 29/12 (333 - 363)
Potato	D3	18/05 – 17/06 (138 – 168)
	D4	30/05 – 29/06 (150 – 180)
	D6	18/04 – 18/05 (108 – 138)
		13/08 – 12/09 (225-255)
	R1	13/05 – 12/06 (133 – 163)
	R2	23/03 – 22/04 (82-112)
	R3	18/04 – 18/05 (108 – 138)
Sunflower	D3*	13/05 – 12/06 (133 - 163)
	D4*	18/05 – 17/06 (138 - 168)
	D5	09/05 – 08/06 (129 – 159)
	R1	09/05 – 08/06 (129 – 159)
	R3	23/04 – 23/05 (113 – 143)

Crop	Scenario	Application window used in modelling
	R4	07/04 – 07/05 (97 - 127)

*maize used as surrogate crop

Table 8.9-22: Tier 2 PEC_{sw} and PEC_{sed} for prosulfocarb sulfoxide following single application to winter cereals (pre-emergence)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, tva} (µg/L)**	Max PEC _{sed} (µg/kg)*
D1	ditch	2.239	Drainage	1.671	2.678
D1	stream	1.417	Drainage	1.040	1.723
D2	ditch	9.868	Drainage	2.334	2.482
D2	stream	6.322	Drainage	1.366	1.468
D3	ditch	< 0.000001	Drainage	< 0.000001	< 0.000001
D4	pond	0.009321	Drainage	0.007816	0.01046
D4	stream	0.01667	Drainage	0.007455	0.01042
D5	pond	0.03390	Drainage	0.02920	0.04954
D5	stream	0.2084	Drainage	0.04296	0.06181
D6	ditch	2.182	Drainage	0.3759	0.5166
R1	pond	0.07442	Run-off	0.04417	0.04897
R1	stream	6.959	Run-off	0.1424	0.9053
R3	stream	9.508	Run-off	0.2704	1.334
R4	stream	1.536	Run-off	0.04592	0.2422

* single applications should be marked.

** two-time as required by ecotox

Table 8.9-23: Tier 2 PEC_{sw} and PEC_{sed} for prosulfocarb sulfoxide following single application to winter cereals (post-emergence)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, tva} (µg/L)**	Max PEC _{sed} (µg/kg)*
D1	ditch	8.048	Drainage	3.965	5.753
D1	stream	5.290	Drainage	2.971	3.797
D2	ditch	6.645	Drainage	1.751	1.757
D2	stream	4.294	Drainage	1.019	1.062
D3	ditch	< 0.000001	Drainage	< 0.000001	< 0.000001
D4	pond	0.2150	Drainage	0.1756	0.2024
D4	stream	0.3837	Drainage	0.1638	0.2006
D5	pond	0.03620	Drainage	0.03120	0.05269
D5	stream	0.2228	Drainage	0.04593	0.06575
D6	ditch	0.7463	Drainage	0.08189	0.1737

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
R1	pond	0.001055	Run-off	0.000633	0.001006
R1	stream	0.9097	Run-off	0.004171	0.04455
R3	stream	7.643	Run-off	0.1951	1.075
R4	stream	1.536	Run-off	0.04592	0.2422

* single applications should be marked.

** two-time as required by ecotox

Table 8.9-24: Tier 2 PEC_{sw} and PEC_{sed} for prosulfocarb sulfoxide following single application to potato

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
D3	ditch	< 0.000001	Drainage	< 0.000001	< 0.000001
D4	pond	0.000007	Drainage	0.000007	0.000032
D4	stream	0.000020	Drainage	0.000019	0.000100
D6, 1st	ditch	1.116	Drainage	0.1047	0.2795
D6, 2nd	ditch	0.02710	Drainage	0.006142	0.01260
R1	pond	0.1137	Run-off	0.04877	0.05684
R1	stream	2.791	Run-off	0.07287	0.4325
R2	stream	0.5735	Run-off	0.01609	0.09312
R3	stream	0.004172	Run-off	0.000194	0.000919

* single applications should be marked.

** two-time as required by ecotox

Table 8.9-25: Tier 2 PEC_{sw} and PEC_{sed} for prosulfocarb sulfoxide following single application to sunflower

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
D3	ditch	< 0.000001	Drainage	< 0.000001	< 0.000001
D4	pond	< 0.000001	Drainage	< 0.000001	0.000004
D4	stream	0.000002	Drainage	0.000002	0.000013
D5	pond	< 0.000001	Drainage	< 0.000001	< 0.000001
D5	stream	< 0.000001	Drainage	< 0.000001	< 0.000001
R1	pond	0.03055	Runoff	0.01305	0.01659
R1	stream	1.186	Runoff	0.03183	0.1285
R3	stream	0.03671	Runoff	0.000983	0.005906
R4	stream	2.223	Runoff	0.08439	0.4277

* single applications should be marked.

** two-time as required by ecotox

8.9.2.2 Diflufenican and its metabolites

Table 8.9-26: Input parameters related to active substance diflufenican and metabolites for PEC_{sw/sed} calculations STEP 1/2 and 3(/4) (if necessary)

Compound	Diflufenican	AE 0542291	AE B107137	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	394	282	283	Y, EFSA, 2007
Saturated vapour pressure (Pa)	0.425 x 10 ⁻⁵ (20°C)	10 ⁻¹⁰	10 ⁻¹⁰	Y, EFSA, 2007
Water solubility (mg/L)	0.05 (20°C)	100	410	Y, EFSA, 2007
Diffusion coefficient in water (m ² /d)	4.3 x 10 ⁻⁵	4.3 x 10 ⁻⁵	4.3 x 10 ⁻⁵	default
Diffusion coefficient in air (m ² /d)	0.43	0.43	0.43	default
K _{foc} (mL/g)	3091 (geomean, n = 10)	130 (geomean, n = 4)	11 (geomean, n = 4)	Y, EFSA, 2007 Geometric mean used in accordance with EFSA Journal 2014;12(5):3662.
Freundlich Exponent 1/n	0.917 (arithmetic mean, n = 10)	0.81 (arithmetic mean, n = 4)	0.73 (arithmetic mean, n = 4)	Y, EFSA, 2007
Plant Uptake	0	0	0	worst case
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	0.05 (MACRO) 0.50 (PRZM)	0.05 (MACRO) 0.50 (PRZM)	default
DT _{50,soil} (d)	128 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n =8)	22.9 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n = 3)	10.3 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n =3)	Y, EFSA, 2007 Geometric mean used in accordance with EFSA Journal 2014;12(5):3662.
DT _{50,water} (d)	175 (geomean, n = 4; Step 2) 1000 (worst case; Step 3-4)	1000 (worst case)	1000 (worst case)	Y, EFSA, 2007 Diflufenican: according to FOCUS SW (2015) for compounds with Koc > 2000 mL/g.
DT _{50,sed} (d)	175 (geomean, n = 4 ; Step 2-4)	1000 (worst case)	1000 (worst case)	Y, EFSA, 2007 Diflufenican: according to FOCUS SW (2015) for compounds with Koc > 2000 mL/g.
DT _{50,whole system} (d)	175	1000 (worst case)	1000 (worst case)	Y, EFSA, 2007

Compound	Diflufenican	AE 0542291	AE B107137	Value in accordance to EU endpoint y/n/ Reference
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 26.3 Water: - Sediment: - Total system: 0.01	Soil: 16.8 Water: 32.6 Sediment: 13.3 Total system: 35.7	Y, EFSA, 2007
Formation fraction in soil	-	1 (from parent)	1 (from parent)	Y, EFSA, 2007

PEC_{sw/sed}

Table 8.9-27: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for diflufenican following single application of GLOB1912H to winter cereals (pre-emergence)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	---	3.33	-	2.88	92.25
Step 2					
Northern Europe	Oct-Feb	1.54	-	1.45	46.36
Southern Europe	Oct-Feb	1.25	-	1.17	37.58
Step 3					
D1	ditch	0.2879	Drainage	0.1606	1.402
D1	stream	0.2501	Drainage	0.03062	0.6336
D2	ditch	0.3069	Drainage	0.08350	1.263
D2	stream	0.2618	Drainage	0.05536	0.8155
D3	ditch	0.2818	Drainage	0.01073	0.1514
D4	pond	0.009742	Drainage	0.007645	0.1277
D4	stream	0.2444	Drainage	0.003362	0.05230
D5	pond	0.009792	Drainage	0.007786	0.08721
D5	stream	0.2637	Drainage	0.004819	0.07345
D6	ditch	0.2850	Drainage	0.07899	0.7374
R1	pond	0.02288	Runoff	0.01851	0.3056
R1	stream	0.1858	Runoff	0.006774	0.3328
R3	stream	0.2580	Runoff	0.01912	13.72
R4	stream	0.1869	Runoff	0.007550	0.2446

* single applications should be marked.

** two-time as required by ecotox

Table 8.9-28: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for diflufenican following single application of GLOB1912H to winter cereals (post-emergence)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	---	3.33	-	2.88	92.25
Step 2					
Northern Europe	Oct-Feb	1.54	-	1.45	46.36
Southern Europe	Oct-Feb	1.25	-	1.17	37.58
Step 3					
D1	ditch	0.2876	Drainage	0.1619	1.378
D1	stream	0.2501	Drainage	0.03075	0.6359
D2	ditch	0.3130	Drainage	0.08613	1.275
D2	stream	0.2437	Drainage	0.02681	0.6295
D3	ditch	0.2817	Drainage	0.01022	0.1451
D4	pond	0.009742	Drainage	0.007635	0.1234
D4	stream	0.2444	Drainage	0.003361	0.05230
D5	pond	0.009782	Drainage	0.007776	0.08666
D5	stream	0.2637	Drainage	0.004819	0.07344
D6	ditch	0.2850	Drainage	0.07892	0.7373
R1	pond	0.02309	Run-off	0.01868	0.3083
R1	stream	0.1858	Run-off	0.006845	0.3327
R3	stream	0.2607	Run-off	0.008159	0.2954
R4	stream	0.1843	Run-off	0.009062	0.2866

* single applications should be marked.

** twa-time as required by ecotox

Table 8.9-29: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for diflufenican following single application of GLOB1912H to potato

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	---	3.33	-	2.88	92.25
Step 2					
Northern Europe	March-May	0.68	-	0.62	20.01
	June-Sept	0.68	-	0.62	20.01
Southern Europe	March-May	1.25	-	1.17	37.58
	June-Sept	0.97	-	0.90	28.79
Step 3					

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
D3	ditch	0.2339	Drainage	0.01261	0.1688
D4	pond	0.009431	Drainage	0.007262	0.1086
D4	stream	0.1931	Drainage	0.002728	0.03350
D6, 1st	ditch	0.2314	Drainage	0.005438	0.08475
D6, 2nd	ditch	0.2352	Drainage	0.03981	0.4032
R1	pond	0.02007	Runoff	0.01766	0.4716
R1	stream	0.1616	Runoff	0.008401	0.5027
R2	stream	0.2140	Runoff	0.004603	5.307
R3	stream	0.2282	Runoff	0.01043	0.4481

* single applications should be marked.

** twa-time as required by ecotox

Table 8.9-30: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for diflufenican following single application of GLOB1912H to sunflower

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	---	3.33	-	2.88	92.25
Step 2					
Northern Europe	March-May	0.68	-	0.62	20.01
Southern Europe	March-May	1.25	-	1.17	37.58
Step 3					
D3	ditch	0.2339	Drainage	0.01280	0.1706
D4	pond	0.009433	Drainage	0.007295	0.08915
D4	stream	0.2003	Drainage	0.001194	0.01657
D5	pond	0.009528	Drainage	0.007425	0.08192
D5	stream	0.2114	Drainage	0.000720	0.01180
R1	pond	0.02187	Runoff	0.01930	0.5152
R1	stream	0.1615	Runoff	0.008814	0.5866
R3	stream	0.2281	Runoff	0.009855	0.5206
R4	stream	0.1974	Runoff	0.02571	0.8154

* single applications should be marked.

** twa-time as required by ecotox

FOCUS Step 4

Table 8.9-31: Global maximum PEC_{sw} values for diflufenican, following single application of GLOB1912H to winter cereals (pre-emergence) according to the central EU zone GAP according to surface water Step 4

PEC _{sw} (µg/L)	Scenario	STEP 4 diflufenican				
Nozzle reduction	Vegetative strip (m)	None	None	None	10	20
	No spray buffer (m)	5	10	20	10	20
None	D1 ditch	0.07945	0.07028	0.07028	-	-
50 %		0.07028	0.07028	-	-	-
75 %		0.07027	-	-	-	-
90 %		-	-	-	-	-
None	D1 stream	0.09137	0.04846	0.04421	-	-
50 %		0.04567	0.04421	-	-	-
75 %		0.04421	-	-	-	-
90 %		-	-	-	-	-
None	D2 ditch	0.1575	0.1575	0.1575	-	-
50 %		0.1575	0.1575	-	-	-
75 %		0.1575	-	-	-	-
90 %		-	-	-	-	-
None	D2 stream	0.1001	0.09928	0.09928	-	-
50 %		0.09928	0.09928	-	-	-
75 %		0.09928	-	-	-	-
90 %		-	-	-	-	-
None	D3 ditch	0.07639	0.04048	0.02103	-	-
50 %		0.03816	0.02024	-	-	-
75 %		0.01908	-	-	-	-
90 %		-	-	-	-	-
None	D4 stream	0.08927	0.04734	0.03271	-	-
50 %		0.04461	0.03271	-	-	-
75 %		0.03271	-	-	-	-
90 %		-	-	-	-	-
None	D5 stream	0.09631	0.05107	0.02652	-	-
50 %		0.04812	0.02552	-	-	-
75 %		0.02408	-	-	-	-
90 %		-	-	-	-	-
None	D6 ditch	0.1051	0.1051	0.1051	-	-
50 %		0.1051	0.1051	-	-	-

PEC _{sw} (µg/L)	Scenario	STEP 4 diflufenican				
Nozzle reduction	Vegetative strip (m)	None	None	None	10	20
	No spray buffer (m)	5	10	20	10	20
75 %	R1 stream	0.1051	-	-	-	-
90 %		-	-	-	-	-
None		0.1190	0.1190	0.1190	0.05324	0.02773
50 %		0.1190	0.1190	-	0.05324	-
75 %	R3 stream	0.1190	-	-	-	-
90 %		-	-	-	-	-
None		0.1363	0.1363	0.1363	0.06220	0.03262
50 %		0.1363	0.1363	-	0.06220	-
75 %	R4 stream	0.1363	-	-	-	-
90 %		-	-	-	-	-
None		0.1693	0.1693	0.1693	0.07642	0.03990
50 %		0.1693	0.1693	-	0.07642	-
75 %		0.1693	-	-	-	-
90 %		-	-	-	-	-

Table 8.9-32: Global maximum PEC_{sw} values for diflufenican, following single application of GLOB1912H to winter cereals (post-emergence) according to the central EU zone GAP according to surface water Step 4

PEC _{sw} (µg/L)	Scenario	STEP 4 diflufenican				
Nozzle reduction	Vegetative strip (m)	None	None	None	10	20
	No spray buffer (m)	5	10	20	10	20
None	D1 ditch	0.07914	0.07245	0.07245	-	-
50 %		0.07245	0.07245	-	-	-
75 %		0.07245	-	-	-	-
90 %		-	-	-	-	-
None	D1 stream	0.09137	0.04846	0.04561	-	-
50 %		0.04566	0.04561	-	-	-
75 %		0.04561	-	-	-	-
90 %		-	-	-	-	-
None	D2 ditch	0.1564	0.1564	0.1564	-	-
50 %		0.1564	0.1564	-	-	-
75 %		0.1564	-	-	-	-

PEC _{sw} (µg/L)	Scenario	STEP 4 diflufenican				
Nozzle reduction	Vegetative strip (m)	None	None	None	10	20
	No spray buffer (m)	5	10	20	10	20
90 %		-	-	-	-	-
None	D2 stream	0.0987	0.0987	0.0987	-	-
50 %		0.0987	0.0987	-	-	-
75 %		0.0987	-	-	-	-
90 %		-	-	-	-	-
None	D3 ditch	0.07635	0.04046	0.02102	-	-
50 %		0.03815	0.02023	-	-	-
75 %		0.01907	-	-	-	-
90 %		-	-	-	-	-
None	D4 stream	0.08927	0.04734	0.03089	-	-
50 %		0.04461	0.03089	-	-	-
75 %		0.03089	-	-	-	-
90 %		-	-	-	-	-
None	D5 stream	0.09631	0.05107	0.02652	-	-
50 %		0.04812	0.02552	-	-	-
75 %		0.02406	-	-	-	-
90 %		-	-	-	-	-
None	D6 ditch	0.1087	0.1087	0.1087	-	-
50 %		0.1087	0.1087	-	-	-
75 %		0.1087	-	-	-	-
90 %		-	-	-	-	-
None	R1 stream	0.1200	0.1200	0.1200	0.05374	0.02798
50 %		0.1200	0.1200	-	0.05374	-
75 %		0.1200	-	-	-	-
90 %		-	-	-	-	-
None	R3 stream	0.1229	0.1229	0.1229	0.05535	0.02892
50 %		0.1229	0.1229	-	0.05535	-
75 %		0.1229	-	-	-	-
90 %		-	-	-	-	-
None	R4 stream	0.1743	0.1743	0.1743	0.07866	0.04108
50 %		0.1743	0.1743	-	0.07866	-
75 %		0.1743	-	-	-	-
90 %		-	-	-	-	-

Table 8.9-33: Global maximum PEC_{sw} values for diflufenican, following single application of GLOB1912H to potatoes according to the central EU zone GAP according to surface water Step 4

PEC _{sw} (µg/L)	Scenario	STEP 4 diflufenican				
Nozzle reduction	Vegetative strip (m)	None	None	None	10	20
	No spray buffer (m)	5	10	20	10	20
None	D3 ditch	0.07664	0.04062	0.02110	-	-
50 %		0.03829	0.03829	-	-	-
75 %		0.01914	-	-	-	-
90 %		-	-	-	-	-
None	D4 stream	0.08127	0.04310	0.03138	-	-
50 %		0.04061	0.04061	-	-	-
75 %		0.03138	-	-	-	-
90 %		-	-	-	-	-
None	D6 ditch, 1st	0.07588	0.04822	0.04822	-	-
50 %		0.04822	0.04822	-	-	-
75 %		0.04822	-	-	-	-
90 %		-	-	-	-	-
None	D6 ditch, 2nd	0.1002	0.1002	0.1002	-	-
50 %		0.1002	0.1002	-	-	-
75 %		0.1002	-	-	-	-
90 %		-	-	-	-	-
None	R1 stream	0.1107	0.1107	0.1107	0.05011	0.02619
50 %		0.1107	0.1107	-	0.05011	-
75 %		0.1107	-	-	-	-
90 %		-	-	-	-	-
None	R2 stream	0.09009	0.04777	0.04141	0.04777	0.02480
50 %		0.04501	0.04501	-	0.02387	-
75 %		0.04141	-	-	-	-
90 %		-	-	-	-	-
None	R3 stream	0.1220	0.1220	0.1220	0.05563	0.02917
50 %		0.1220	0.1220	-	0.05563	-
75 %		0.1220	-	-	-	-
90 %		-	-	-	-	-

Table 8.9-34: Global maximum PEC_{sw} values for diflufenican, following single application of GLOB1912H to sunflower according to the central EU zone GAP according to surface water Step 4

PEC _{sw} (µg/L)	Scenario	STEP 4 diflufenican				
Nozzle reduction	Vegetative strip (m)	None	None	None	10	20
	No spray buffer (m)	5	10	20	10	20
None	D3 ditch	0.07666	0.4062	-	-	-
50 %		0.03830	-	-	-	-
75 %		-	-	-	-	-
90 %		-	-	-	-	-
None	D4 stream	0.08432	0.04472	-	-	-
50 %		0.04213	-	-	-	-
75 %		-	-	-	-	-
90 %		-	-	-	-	-
None	D5 stream	0.08897	0.04718	0.02450	-	-
50 %		0.04446	0.02358	-	-	-
75 %		-	-	-	-	-
90 %		-	-	-	-	-
None	R1 stream	0.1148	0.1148	0.1148	0.05201	0.02721
50 %		0.1148	0.1148	-	0.05201	0.02721
75 %		-	-	-	-	-
90 %		-	-	-	-	-
None	R3 stream	0.1284	0.1284	0.1284	0.05852	0.03069
50 %		0.1284	0.1284	-	0.05852	0.03069
75 %		-	-	-	-	-
90 %		-	-	-	-	-
None	R4 stream	0.1974	0.1974	0.1974	0.08974	0.04702
50 %		0.1974	0.1974	-	0.08974	0.04702
75 %		-	-	-	-	-
90 %		-	-	-	-	-

From the aquatic risk assessment in section B9, it is clear that algae are the most sensitive aquatic organism when exposed to diflufenican. Based on higher-tier laboratory studies with peak exposure followed by a recovery phase, it was decided at the EU level that the risk for algae may be considered acceptable provided that:

- The peak exposure is below 0.42 µg diflufenican /L
- The other exposure peaks do not exceed the overall NOEC for all species tested, 0.1 µg/L within 3 days.

- The exposure does not persist for > 3 days (the duration of exposure in the study on which these assumptions were based). The exposure above the overall NOEC of 0.1 µg/L should be then ≤ 3 days.

Scenarios with a maximum PEC_{sw} below 0.1 µg/L automatically fulfil these conditions. However, FOCUS profiles of scenarios with a maximum PEC_{sw} above 0.1 µg/L (but below 0.42 µg/L) were analysed using EPAT v1.2 in order to check if they fulfil these conditions. The results can be found in the table below. Graphs of each FOCUS profile with plotted thresholds of 0.42 µg/L and 0.1 µg/L can be found in Appendix 3.

Table 8.9-35: Analysis of FOCUS profiles with a maximum PEC_{sw} above 0.1 µg/L but below 0.42 µg/L using EPAT v1.2 using a 5 m bufferzone

Use	Scenario		Peaks above 0.1 µg/L	Max. peak concentration if above 0.1 µg/L	Interval between peaks above 0.1 µg/L (days)	Duration of peak above 0.1 µg/L (days)	Total duration of peaks above 0.1 µg/L within one exposure-recovery time frame (days)
Winter cereals, pre-emergence	STEP 4 – 5m	D2 ditch	1	0.1254	-	0.167	0.167
			2	0.1130	5.833	0.084	0.458
			3	0.1142	0.875	0.166	
			4	0.1239	0.834	0.208	
			5	0.1221	18.833	0.167	0.167
			6	0.1067	34.875	0.083	0.083
			7	0.1148	18.917	0.125	0.125
			8	0.1263	3.875	0.167	0.167
			9	0.1196	17.791	0.167	0.292
			10	0.1175	0.833	0.125	
			11	0.1245	3.875	0.167	0.167
			12	0.1333	24.917	0.416	0.416
			13	0.1183	4.542	0.125	0.125
			14	0.1028	98.25	0.167	0.167
			15	0.1089	18.583	0.167	0.167
			16	0.1083	35.75	0.291	0.458
			17	0.1145	1.667	0.167	
			18	0.1219	9.791	0.209	0.209
			19	0.1104	8.791	0.125	0.125
			20	0.1129	3.875	0.125	0.334
			21	0.1302	0.875	0.209	
			22	0.1116	3.791	0.084	0.834
			23	0.1405	1.916	0.292	
			24	0.1374	1.667	0.291	
			25	0.1219	2.75	0.167	0.457
			26	0.1230	16.792	0.166	
			27	0.1375	2.834	0.291	

			28	0.1401	15.709	0.291	0.291
			29	0.1055	32.792	0.042	0.042
			30	0.1031	23.958	0.083	0.083
			31	0.1196	7.875	0.167	0.376
			32	0.1315	0.833	0.209	
			33	0.1448	18.791	0.334	0.334
			34	0.1575	8.666	0.417	0.667
			35	0.1452	2.583	0.25	
		D2 stream	1	0.1001	-	0.042	0.042
		D6 ditch	1	0.1051	-	0.083	0.083
		R1 stream	1	0.1190	-	0.334	0.334
			2	0.1050	35.625	0.583	0.583
		R3 stream	1	0.1363	-	0.458	1.832
			2	0.1292	0.542	0.916	
			3	0.1132	0.125	0.125	
			4	0.1229	0.834	0.333	
			5	0.1096	16.708	0.334	0.334
			6	0.1054	9.666	0.334	0.334
		R4 stream	1	0.1693	-	0.541	0.958
			2	0.1558	0.500	0.417	
			3	0.1169	87.542	0.625	0.625
Winter cereals, post-emergence	STEP 4 – 5m	D2 ditch	1	0.1261	-	0.25	0.25
			2	0.1158	5.791	0.125	0.499
			3	0.1167	0.834	0.166	
			4	0.1242	0.834	0.208	
			5	0.1218	18.833	0.167	0.167
			6	0.1083	34.875	0.125	0.125
			7	0.1143	18.875	0.125	0.333
			8	0.1227	3.875	0.208	
			9	0.1161	17.75	0.167	0.292
			10	0.1142	0.833	0.125	
			11	0.1190	3.875	0.167	0.167
			12	0.1243	24.917	0.416	0.416
			13	0.1119	4.542	0.125	0.125
			14	0.1031	154.917	0.083	0.083
			15	0.1101	9.875	0.125	0.125
			16	0.1057	3	0.292	0.292
			17	0.1017	9.583	0.042	0.209
			18	0.1191	0.916	0.167	
			19	0.1009	3.833	0.042	0.626
			20	0.1310	1.958	0.25	
			21	0.1276	1.75	0.209	
			22	0.1112	2.791	0.125	0.334
			23	0.1131	16.875	0.125	
			24	0.1291	2.875	0.209	0.292
			25	0.1331	15.791	0.209	
			26	0.1132	64.791	0.125	
			27	0.1262	0.875	0.167	

			28	0.1418	18.875	0.292	0.292
			29	0.1564	8.666	0.375	0.625
			30	0.1434	2.625	0.25	
		D6 ditch	1	0.1087	-	0.083	0.083
		R1 stream	1	0.1200	-	0.334	0.334
			2	0.1061	35.625	0.583	0.583
		R3 stream	1	0.1229	-	0.417	0.417
			2	0.1186	9.583	0.375	0.375
		R4 stream	1	0.1743	-	0.541	0.958
			2	0.1626	0.500	0.417	
			3	0.1219	87.542	0.625	0.625
Potatoes	STEP 4 – 5m	D6 ditch 2 nd	1	0.1002	-	0.042	0.042
		R1 stream	1	0.1107	-	0.458	0.458
			2	0.1008	9.583	0.417	0.417
		R3 stream	1	0.1220	-	0.791	0.791
Sunflower	STEP 4 – 5m	R1 stream	1	0.1148	-	0.458	0.458
			2	0.1014	5.583	0.250	0.250
			3	0.1044	3.709	0.458	0.458
		R3 stream	1	0.1284	-	0.791	0.791
		R4 stream	1	0.1974	-	0.791	0.791
			2	0.1681	12.209	0.708	0.708
			3	0.1441	9.292	0.583	2.124
			4	0.1444	2.417	0.583	
			5	0.1363	0.417	0.958	
			6	0.1138	4.083	0.417	0.751
			7	0.1075	0.583	0.334	

Metabolites of diflufenican

Table 8.9-36: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for AE 0542291 following single application to winter cereals (pre-emergence)

Scenario	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
FOCUS					
Step 1	---	2.40	-	2.38	3.12
Step 2					
Northern Europe	Oct-Feb	1.06	-	1.05	1.38
Southern Europe	Oct-Feb	0.85	-	1.10	0.84

* single applications should be marked.

** twa-time as required by ecotox

Table 8.9-37: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for AE 0542291 following single application to winter cereals (post-emergence)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominat entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	---	2.40	-	2.38	3.12
Step 2					
Northern Europe	Oct-Feb	1.06	-	1.05	1.38
Southern Europe	Oct-Feb	0.85	-	1.10	0.84

* single applications should be marked.

** twa-time as required by ecotox

Table 8.9-38: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for AE 0542291 following single application to potato

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominat entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	---	2.40	-	2.38	3.12
Step 2					
Northern Europe	March-May	0.42	-	0.42	0.55
	June-Sept	0.42	-	0.42	0.55
Southern Europe	March-May	0.85	-	0.84	1.10
	June-Sept	0.64	-	0.63	0.83

* single applications should be marked.

** twa-time as required by ecotox

Table 8.9-39: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for AE 0542291 following single application to sunflower

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominat entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	---	2.40	-	2.38	3.12
Step 2					
Northern Europe	March-May	0.42	-	0.42	0.55
Southern Europe	March-May	0.85	-	0.84	1.10

* single applications should be marked.

** twa-time as required by ecotox

Table 8.9-40: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for AE B107137 following single application to winter cereals (pre-emergence)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominat entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	---	5.66	-	5.61	0.62
Step 2					
Northern Europe	Oct-Feb	2.63	-	2.61	0.29
Southern Europe	Oct-Feb	2.12	-	2.11	0.23

* single applications should be marked.

** twa-time as required by ecotox

Table 8.9-41: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for AE B107137 following single application to winter cereals (post-emergence)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominat entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	---	5.66	-	5.61	0.62
Step 2					
Northern Europe	Oct-Feb	2.63	-	2.61	0.29
Southern Europe	Oct-Feb	2.12	-	2.11	0.23

* single applications should be marked.

** twa-time as required by ecotox

Table 8.9-42: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for AE B107137 following single application to potato

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominat entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	---	5.66	-	5.61	0.62
Step 2					
Northern Europe	March-May	1.11	-	1.11	0.12
	June-Sept	1.11	-	1.11	0.12
Southern Europe	March-May	2.12	-	2.11	0.23
	June-Sept	1.62	-	1.61	0.18

* single applications should be marked.

** twa-time as required by ecotox

Table 8.9-43: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for AE B107137 following single application to sunflower

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominat entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	---	5.66	-	5.61	0.62
Step 2					
Northern Europe	March-May	1.11	-	1.11	0.12
Southern Europe	March-May	2.12	-	2.11	0.23

* single applications should be marked.

** two-time as required by ecotox

PEC_{sw/sed} of GLOB1912H

The PEC_{sw} of the formulation GLOB1912H was also calculated. The calculator tool from the FOCUS SWASH model was used for this purpose. The density of the product is 1.0097 g/mL, so the application rate of the formulation is 3231 g/ha. These PEC_{sw} were calculated for the ditch, pond and stream scenarios. On top, to allow for the 20% spray drift contribution from the upstream catchment in the case of streams, the drift values of the calculator have been multiplied with a factor 1.2 for the stream scenario. The results of these calculations are provided below in the table below.

Table 8.9-44: Maximum PEC_{sw} for GLOB1912H

Cropping scenario	Buffer zone	FOCUS scenario	% drift	Max. PEC _{sw} (µg/L)
Winter cereals/Potatoes/Sunflower, 1 x 3.2 L/ha	1 m	Ditch	1.9274	20.7580
		Pond	0.3282	1.0604
		Stream	1.9274	20.7580
			-	24.9096*
	5m	Ditch	0.5224	5.6266
		Pond	0.1896	0.6124
		Stream	0.5224	5.6266
			-	6.7519*

*taking into account the 20% contribution from the upstream catchment

8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

Review Comments:

The data on atmospheric degradation and behaviour in air for prosulfocarb and diflufenican provided by the Applicant are considered acceptable. The justification for non-assessment via volatilization is accepted. The diflufenican is regarded as non-volatile and, consequently, exposure of adjacent surface waters and terrestrial ecosystems by diflufenican due to volatilization with subsequent deposition is not expected.

Table 0-1 Summary of atmospheric degradation and behaviour - prosulfocarb

Compound	Prosulfocarb
Direct photolysis in air	Not studied – no data requested
Quantum yield of direct phototransformation	Not required
Photochemical oxidative degradation in air	DT50 (h): 3.9 derived by the Atkinson model
Volatilisation	From plant surfaces: 46.7% had volatilised from leaf surfaces after 24 h From soil surfaces: 18% had volatilised after 24 h
Metabolites	No available data – no data requested

The vapour pressure at 20 °C of the active substance prosulfocarb is $> 10^{-4}$ Pa. Hence the active substance prosulfocarb is regarded as volatile (volatilisation from soil and plant surfaces). Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance prosulfocarb due to volatilization with subsequent deposition should be considered. However, due to the short half-life of prosulfocarb (3.9 hours), its transport via air is expected to be low.

Table 0-2 Summary of atmospheric degradation and behaviour - diflufenican

Compound	Diflufenican
Direct photolysis in air	Not studied – no data requested
Quantum yield of direct phototransformation	Not studied – no data requested
Photochemical oxidative degradation in air	DT50 (d): 3.3 derived by the Atkinson model OH (12h) concentration assumed = $1.5 \times 10^6 \text{ cm}^{-3}$
Volatilisation	Vapour pressure (Pa): 4.25×10^{-6} Henry's Law Constant (Pa.m ³ /mol): $> 1.18 \times 10^{-2}$ Volatilisation from plant surfaces and soil was negligible (plants: 0.3% AR after 24 h, soil: 0.0-0.005% AR after 24 h)
Metabolites	Soil anaerobic metabolite 2,4-difluoroaniline was found to be very volatile and may need to be assessed for the air compartment and for transport through air when prolonged anaerobic conditions are expected to occur in soil.

The vapour pressure at 20 °C of the active substance diflufenican is $< 10^{-5}$ Pa. Hence the active substance diflufenican is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance diflufenican due to volatilization with subsequent deposition should not be considered.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2.4	Truyens, S	2021	Estimations of the PECgw of prosulfocarb, diflufenican and relevant metabolites GLOB1912HGW Globachem NV non GLP Unpublished	N	Globachem NV
KCP 9.2.5	Truyens, S	2021 Update July 2022	Estimations of the PECsw of prosulfocarb, diflufenican and relevant metabolites GLOB1912HSW Globachem NV non GLP Unpublished	N	Globachem NV

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
None					

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

List of data relied on not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

Appendix 2 Detailed evaluation of the new Annex II studies

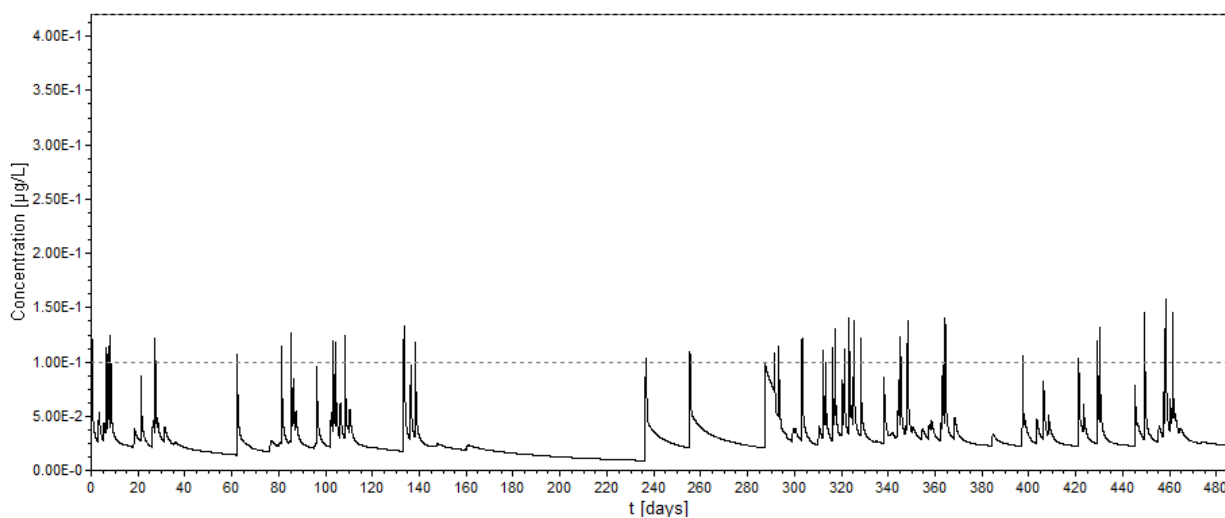
No new studies were submitted.

Appendix 3 Additional information provided by the applicant (e.g. detailed modelling data)

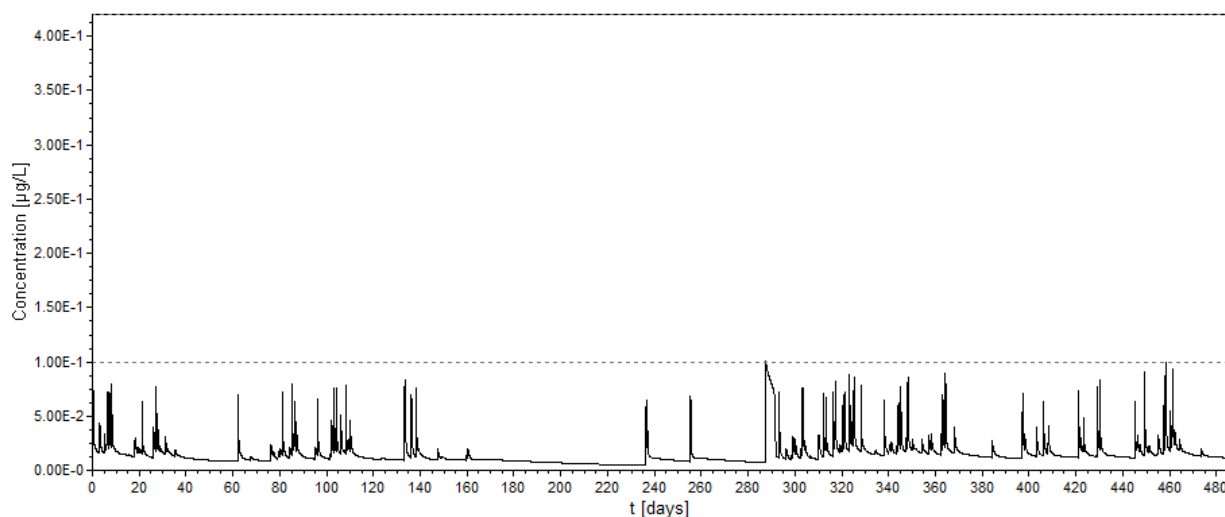
FOCUS profiles - EPAT graphs (5 m bufferzone)

Winter cereals – pre-emergence

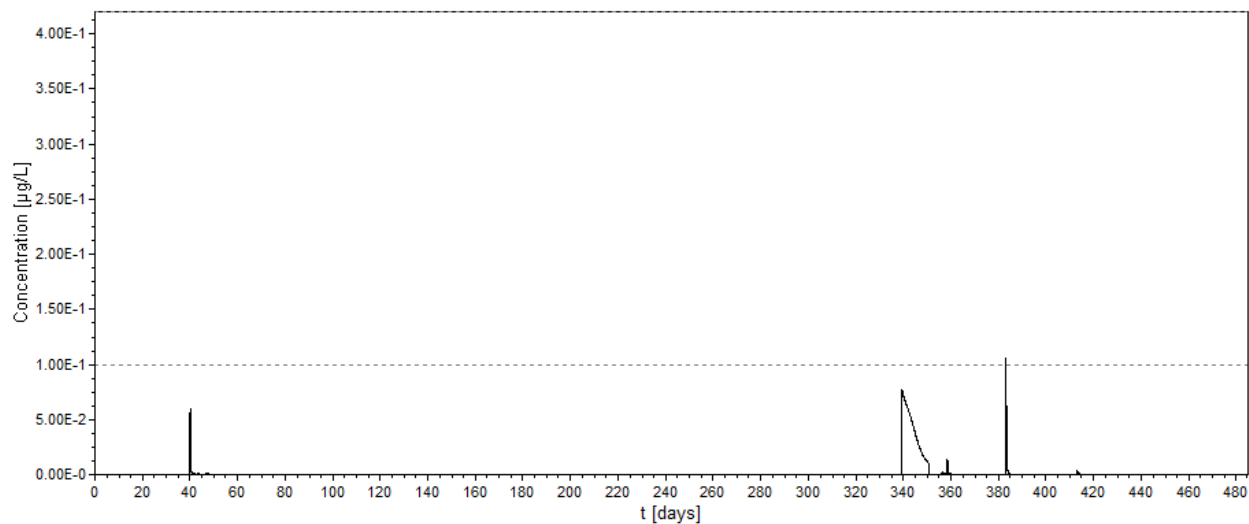
D2 ditch



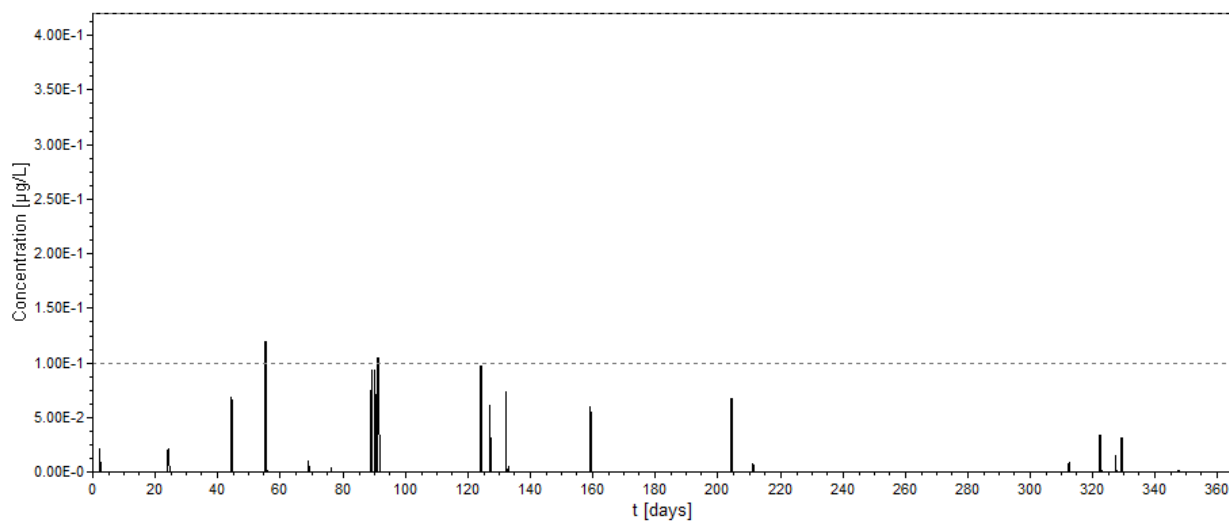
D2 stream



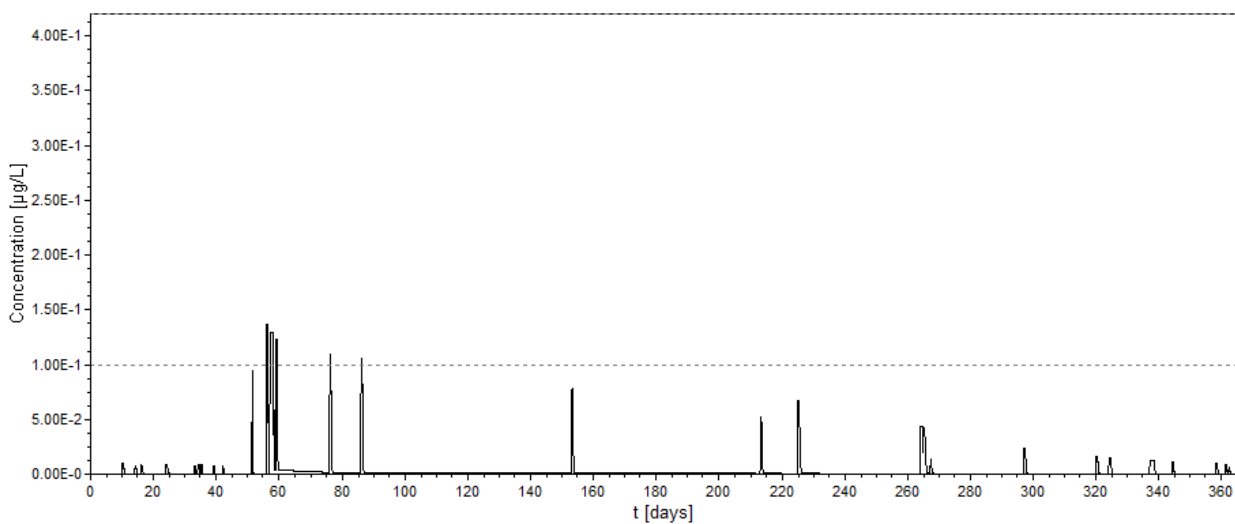
D6 ditch



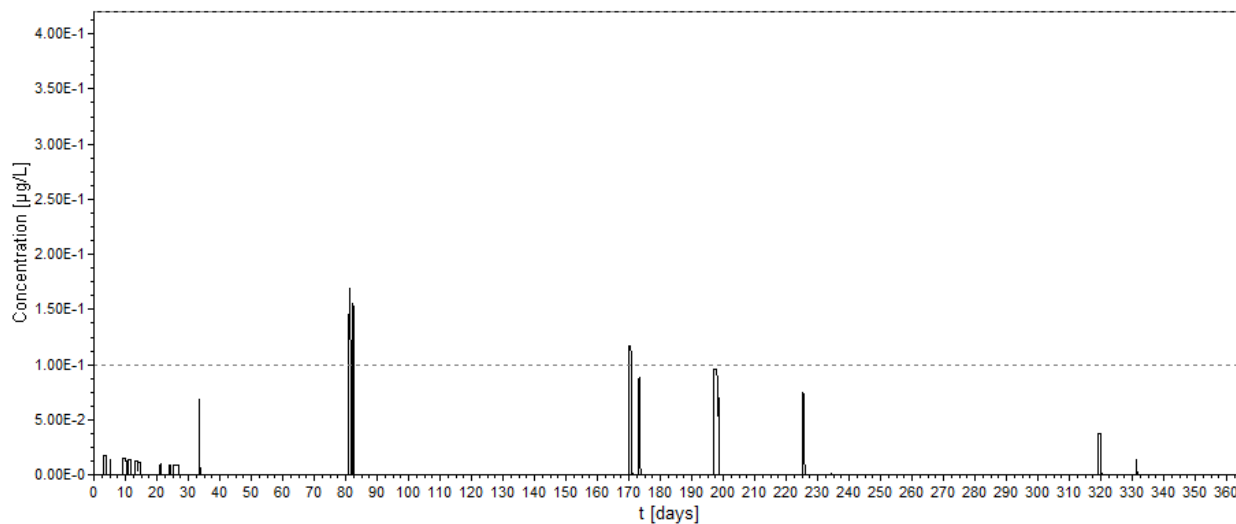
R1 stream



R3 stream

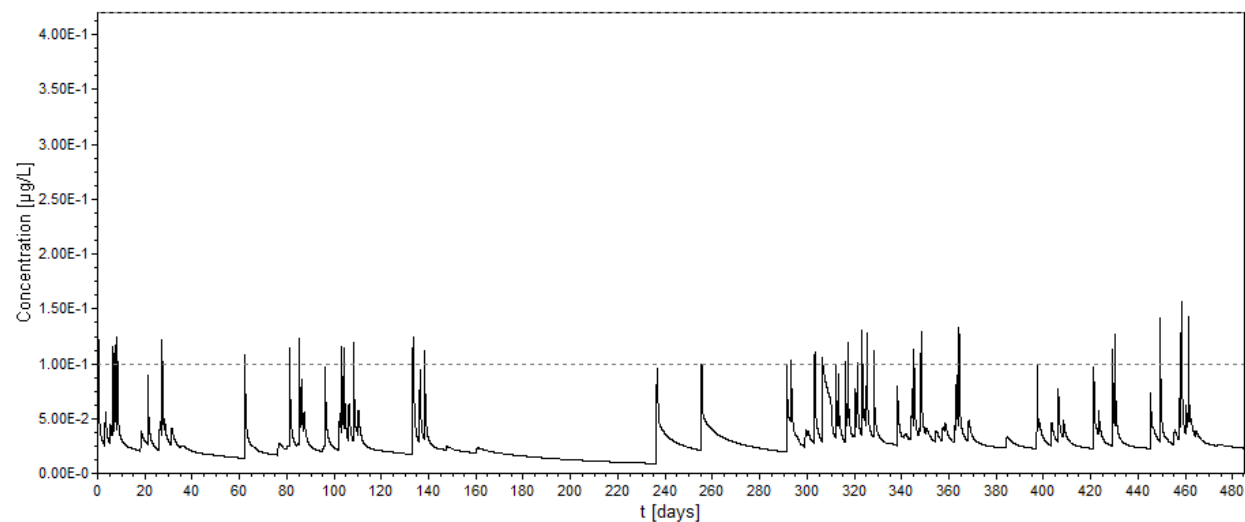


R4 stream

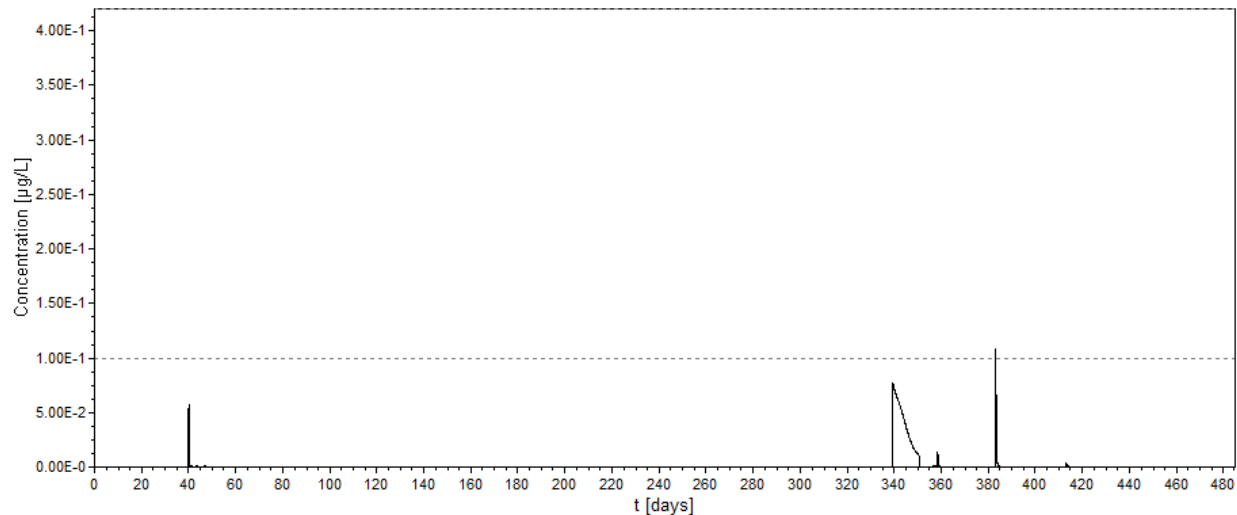


Winter cereals – post-emergence

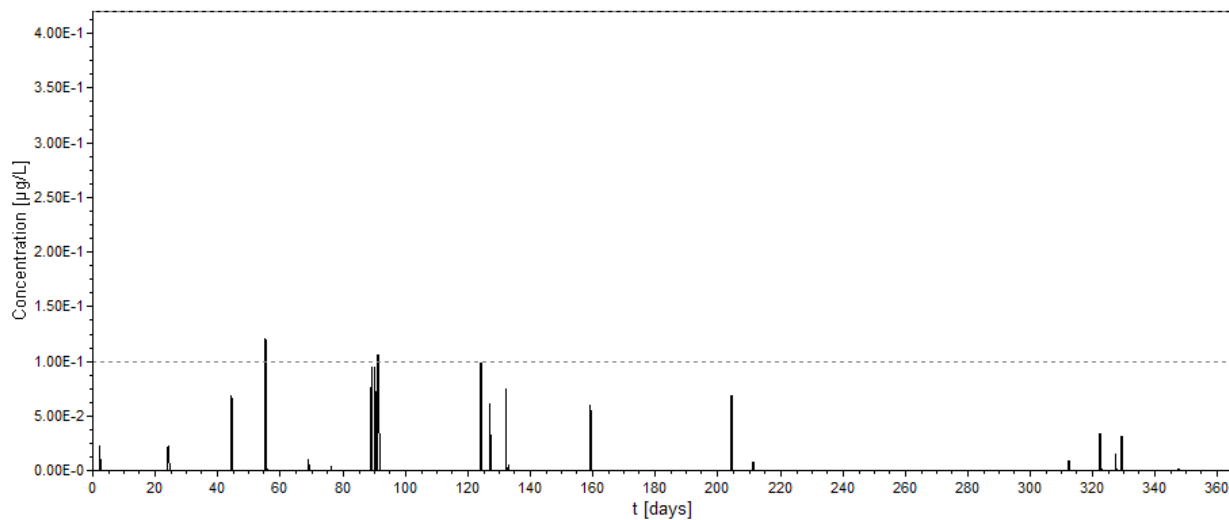
D2 ditch



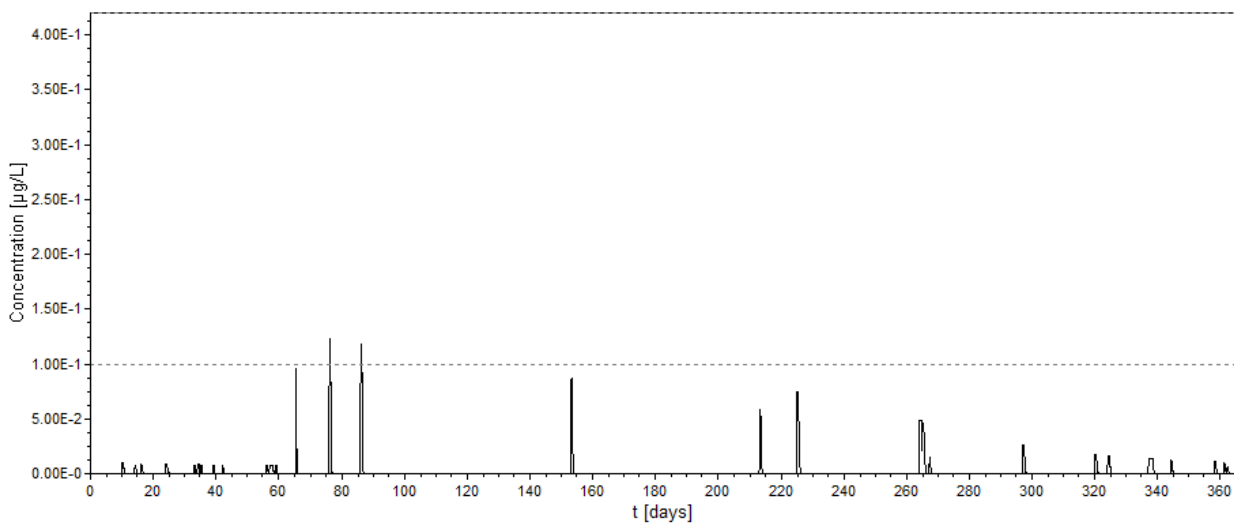
D6 ditch



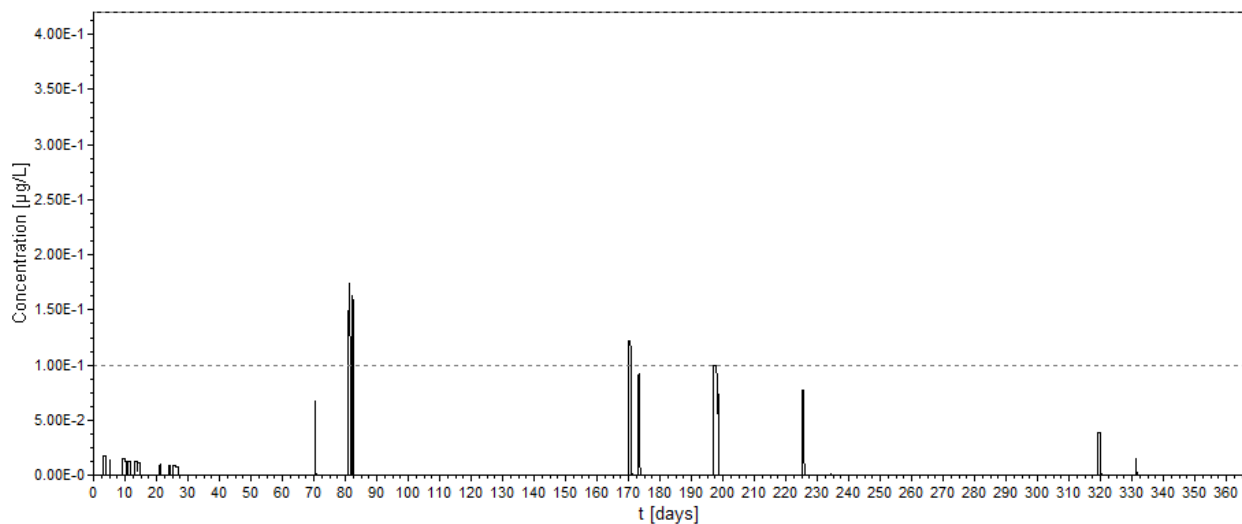
R1 stream



R3 stream

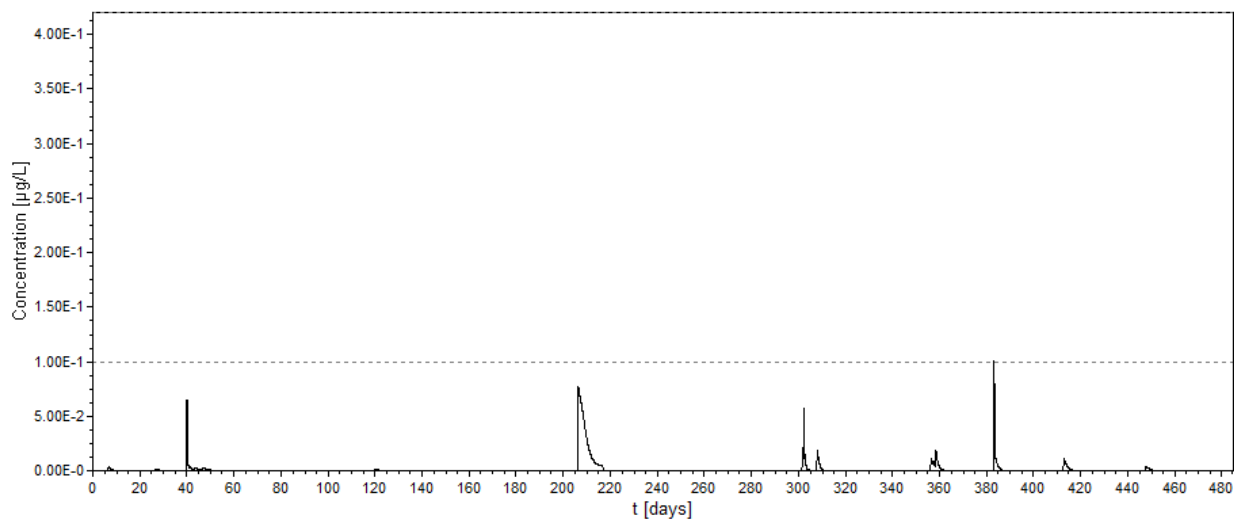


R4 stream

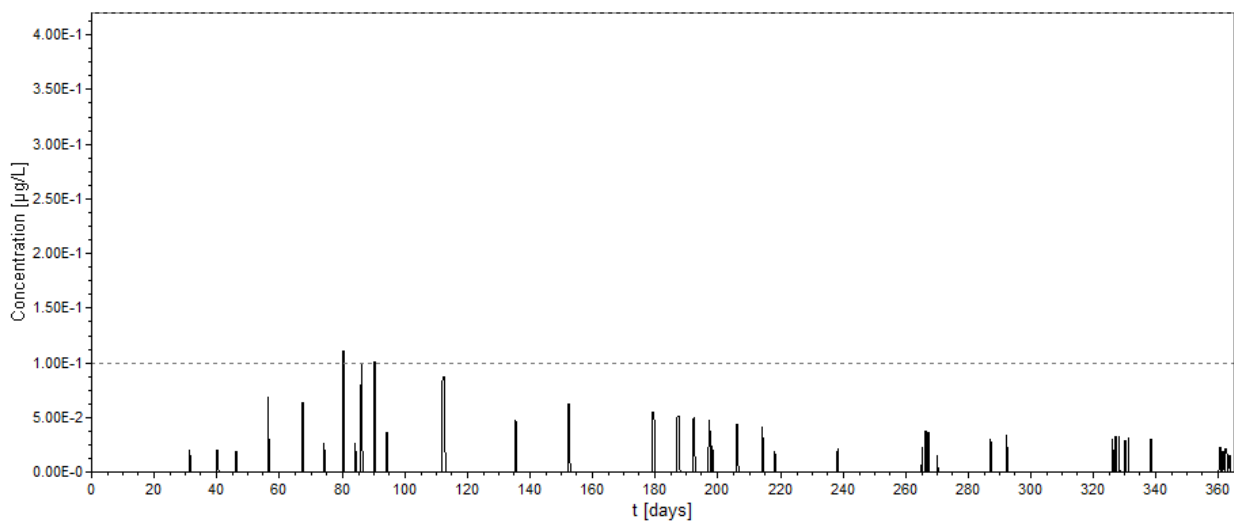


Potatoes

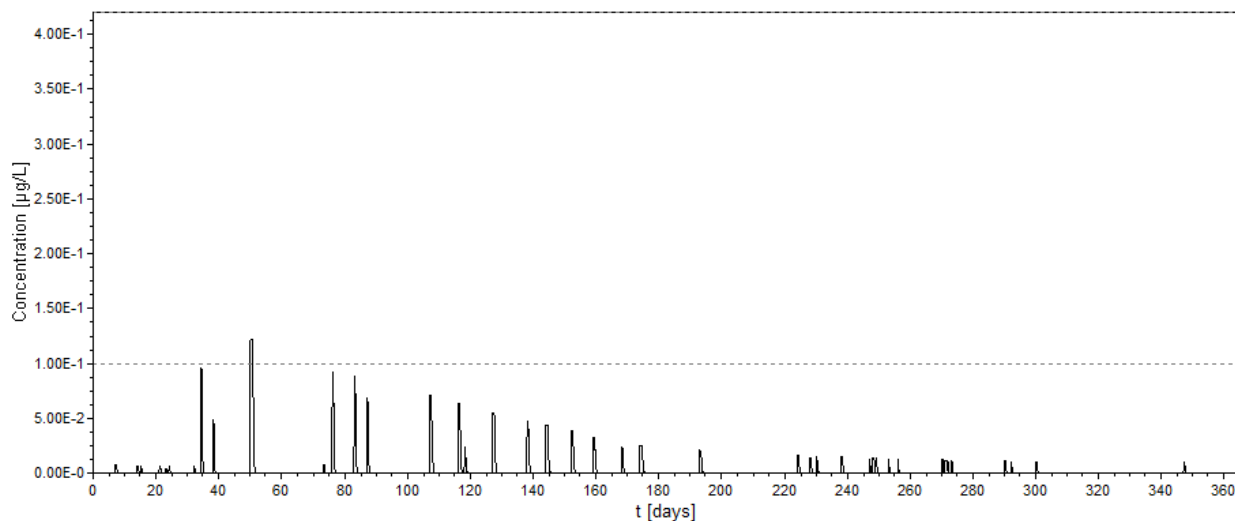
D6 ditch 2nd



R1 stream

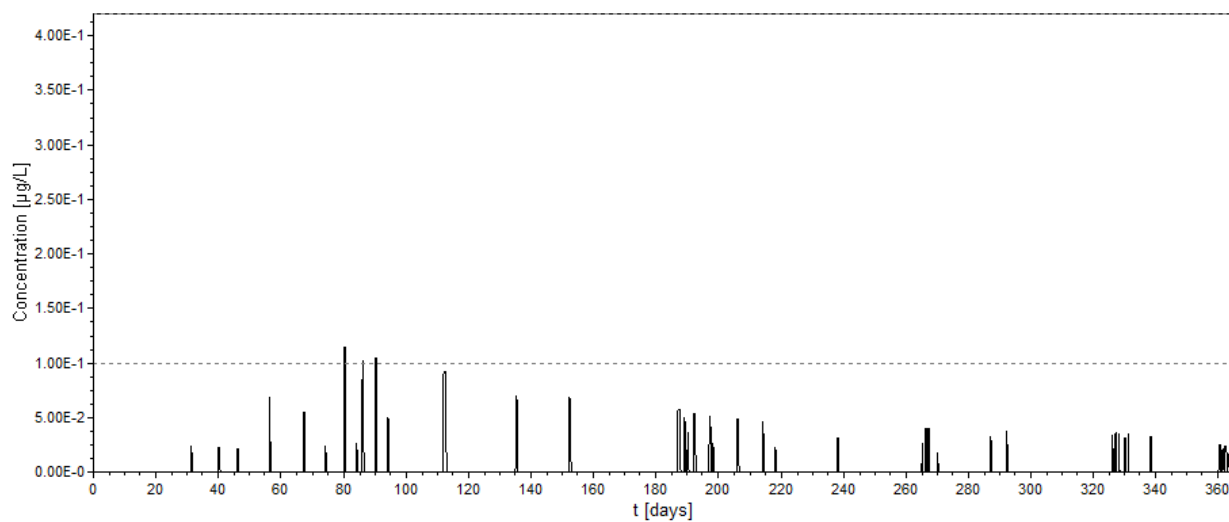


R3 stream

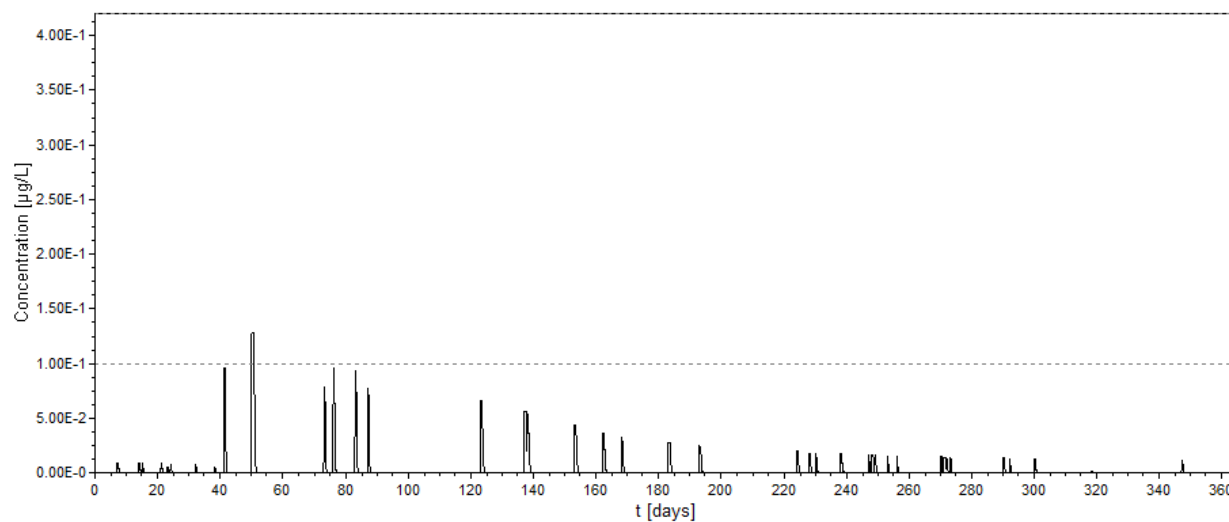


Sunflower

R1 stream



R3 stream



R4 stream

